MISSISSIPPI BOARD OF PHARMACY

MINUTES

November 16, 2023

The Mississippi Board of Pharmacy (Board) met at 9:00 a.m. on Thursday, November 16, 2023 at the Board offices, 6360 I-55 N. Suite 400, Jackson, MS 39211. The following members were present: Ronnie Bagwell – President, Tony Waits – Vice-President, Ryan Harper – Secretary, Jillian Foster, Craig Sartin, David Hudson, and Michael Gilbow.

❖ Motion by Board Member Tony Waits, 2nd by Board Member David Houston to approve the Agenda for this meeting and the Website Declaration of this meeting to be placed in the minutes. All in favor See attached.

REGULATION WORKING GROUP

Todd Dear, Associate Director, presented the following regulations:

Article XXXI

Upon recommendation by staff, the Board unanimously adopted Article XXXI as a final regulation.

Motion by Board Member Ryan Harper, 2nd by Board Member Craig Sartin, to table proposed Administrative Rule and regulations, Articles XXX and XXXV. All in favor.

Eugene Brown, Jr., License to Practice Pharmacy Number E-08931

Upon a motion by Board Member Ryan Harper and a 2nd by Board Member Craig Sartin, the Board voted unanimously to go into executive session pursuant to Section 25-41-7(4)(b) for the purposes of discussing appealable order of the Board. On a motion by Board Member Jillian Foster and a 2nd by Board Member Mike Gilbow, the Board voted unanimously to rise from executive session and enter open session. It was reported that no action was taken during the executive session. After an administrative hearing on this matter, the Board issued the attached Order.

Pharmcore, Inc. dba Hallandale Pharmacy, Permit to Operate as a Pharmacy, Permit Number 15930/7.1

Upon a motion by Board member Jillian Foster and a 2nd by Board member Tony Waits, the Board voted unanimously to go into executive session pursuant to Section 25-41-7(4)(b) for the purposes of discussing appealable order of the Board. On a motion by Board member Tony Waits and a 2nd

by Board member Ryan Harper, the Board voted unanimously to rise from executive session and enter open session. It was reported that no action was taken during the executive session. After an administrative hearing on this matter, the Board issued the attached Order.

Billy R. Calvert, License to Practice Pharmacy Number E-06750

Prior to any administrative hearings being conducted before the Board, Executive Director Susan McCoy stepped down from the Board table.

Upon a motion by Board member Mike Gilbow and a 2nd by Board member Tony Waits, the Board voted unanimously to go into executive session pursuant to Section 25-41-7(4)(b) for the purposes of discussing appealable order of the Board. On a motion by Board member Ryan Harper and a 2nd by Board member Tony Waits, the Board voted unanimously to rise from executive session and enter open session. It was reported that no action was taken during the executive session.

A motion was made by Board Member Craig Sartin and a 2nd by Ronnie Bagwell, to reject the proposed settlement. Ronnie Bagwell and Craig Sartin voted for the motion. Ryan Harper, Jillian Foster, Tony Waits, David Hudson, and Mike Gilbow voted against the motion. Motion was rejected.

Upon a motion by Board member Tony Waits and a 2nd by Ryan Harper, the Board voted to approve the proposed agreed settlement order with Billy R. Calvert. Ryan Harper Jillian Foster, Tony Waits, David Hudson, and Mike Gilbow voted for motion. Ronnie Bagwell and Craig Sartin voted against the motion.

See the attached Settlement Order.

Motion to recess was made by Board Member Craig Sartin, 2nd by David Hudson. All in favor.

Recess at 12:01 p.m.

Meeting called to order at 12:48 p.m.

Board Member Mike Gilbow left the meeting at 1:50 p.m. and did not participate in the decision or order for the following administrative hearings.

The following administrative hearings were conducted together without objection from either Respondent. Prior to any administrative hearings being conducted before the Board, Executive Director Susan McCoy stepped down from the Board table.

Billy R. Calvert, License to Practice Pharmacy Number E-06750 Mississippi Sports Medicine Surgery Center, Pharmacy Permit Number 12956/13.3 Presentation of administrative hearing.

Motion to recess was made by Board Member Tony Waits, 2nd by Craig Sartin. All in favor.

Recess at 2:19 p.m. Meeting called to order at 2:27 p.m.

Upon a motion by Board Member Craig Sartin and a 2nd by Board Member David Hudson, the Board voted unanimously to go into executive session pursuant to Section 25-41-7(4)(b) for the purposes of discussing appealable order of the Board. On a motion by Board Member Ryan Harper

and a 2nd by Board Member Craig Sartin, the Board voted unanimously to rise from executive session and enter open session. It was reported that no action was taken during the executive session.

After an administrative hearing on the matter of Billy R. Calvert, the Board issued the attached order.

After an administrative hearing on the matter of Mississippi Sports Medicine Surgery Center a upon a motion by Board Member David Hudson and a 2nd by Board Member Ryan Harper, the Board voted unanimously to remand the matter back to the Investigations Review Committee (IRC) for further considerations.

The Board adjourned at 3:58 p.m.

These November 16, 2023, MINUTES of the Board are hereby approved this the 18th day of January, 2024.

Ronnie Bagwell, President

Tony Wants, Vice-President

Ryan Harper, Secretary

Jillian Foster

Craig Sartin

David Hudson

Michael Gilbow

Mississippi Board of Pharmacy November 16, 2023

AGENDA

- I. CALL TO ORDER/ESTABLISH A QUORUM
 - PRAYER AND PLEDGE
 - WELCOME AND SPECIAL INTRODUCTIONS
- II. WEBSITE DECLARATION
- III. REGULATORY WORKGROUP
 - Article XXXI
 - Administrative Rules
 - Article XXX
 - Article XXXV

IV. RESPONDENTS

•	Eugene Brown Jr.	Respondent
•	Hallandale Pharmacy	Respondent
•	Billy R. Calvert (Sports Med Pharmacy)	Respondent
•	Billy R. Calvert (Surgery Center)	Respondent
•	MS Sports Medicine Surgery Center	Respondent

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Meetings of the Mississippi Board of Pharmacy will be held in the Board Room of the Mississippi Board of Pharmacy, 6311 Ridgewood Road, Suite E

401, Jackson, Mississippi.

Board Meetings for the first half of 2024 will be held on the following dates at 9:00 a.m.:

- January 18, 2024
- March 28, 2024
- May 23, 2024

The meetings of the Mississippi Board of Pharmacy are open to the public.

To subscribe to the Mississippi Public Meeting Notice webpage please

visit: https://www.ms.gov/dfa/pmn

Board Meeting Agendas and Minutes

Posted agendas are proposed and subject to change. MBP Board Meeting minutes will be posted after they are approved at the following Board Meeting.

	Meeting Date	Agenda	Minutes
MBP January 2024	18	Agenda	
MBP November 2023	16	<u>Agenda</u>	
MBP November 2023	15	Agenda	
MBP October 2023	19	<u>Agenda</u>	Minutes
MBP September 2023	21	Agenda	Minutes
MBP July 2023	13	<u>Agenda</u>	<u>Minutes</u>
MBP May 2023	18	Agenda	Minutes
MBP March 2023	23	Agenda	Minutes
MBP January 2023	19	Agenda	Minutes
MBP December 2022	06	<u>Agenda</u>	Minutes
MBP November 2022	17	Agenda	Minutes
MBP September 2022	28	Agenda	Minutes
MBP September 2022	15	Agenda	Minutes
MBP September 2022	14		Minutes
MBP September 2022	02		Minutes
MBP July 2022	21	<u>Agenda</u>	<u>Minutes</u>
MBP May 2022	12	<u>Agenda</u>	<u>Minutes</u>
MBP May 2022	11	<u>Agenda</u>	Minutes
MBP March 2022	17	<u>Agenda</u>	<u>Minutes</u>

TITLE 30: PROFESSIONS AND OCCUPATIONS PART 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS

ARTICLE XXXI COMPOUNDING GUIDELINES

Every pharmacy permitted by the Mississippi Board of Pharmacy engaged in the compounding of pharmaceuticals that is not a licensed 503B pharmacy following good manufacturing practices (GMP) shall comply with USP 795, USP 797, and USP 800 when compounding in the scope of those chapters. The designated facility USP representative must be a pharmacist licensed in the State of Mississippi.

GENERAL PROVISIONS

- A. Prior to engaging in the compounding of pharmaceuticals, a pharmacy shall obtain a compounding certificate from the Mississippi Board of Pharmacy.
 - To obtain a compounding certificate, an applicant must complete a compounding certificate application.
 - ii. A compounding certificate will expire when the pharmacy permit expires and can be renewed at the time a pharmacy permit is renewed.
 - iii. Compounding, without obtaining the compounding certificate, shall be grounds for disciplinary action.
 - iv. Every pharmacy that engages in compounding shall submit a compounding statistical report to the Board on or about January 31st of each year on a form prescribed by the Board.
 - v. Failure to submit the report as required by this regulation shall be grounds for disciplinary action.
 - vi. A compounding certificate shall become inactive if a pharmacy fails to compound any prescriptions in a calendar year. A pharmacy may not compound prescriptions with an inactive compounding certificate. A pharmacy may petition the Board to activate a compounding certificate that is inactive.
 - vii. Any pharmacy with an active compounding certificate is subject to a compounding inspection by the Board.
- B. Based on the existence of a pharmacist/patient/practitioner relationship and the presentation of a valid prescription, or in anticipation of prescription medication orders based on routine, regularly observed prescribing patterns, a pharmacy may compound, for an individual patient, medications that are not commercially available in the marketplace. Compounding and manufacturing, as defined within the regulations, are not permitted in the same facility. A pharmacy may not Compound a Drug that appears on the FDA List of Drugs withdrawn or removed from the market for Safety Reasons or on the FDA List of Drug products that present demonstrable difficulties in compounding.
- C. For the purpose of this Article, flavoring is not considered compounding. In addition, the combining of commercially manufactured, ready- to-use products shall be exempt from USP 795 compounding standards under the following conditions:
 - i. No more than four (4) commercially manufactured ready-to-use products (that have not been manipulated) are used;
 - ii. Compounding is not done in anticipation of medication orders;
 - iii. Must follow USP 795 beyond use dates (BUDs);

- iv. A valid prescription shall serve as the compounding record;
- v. The prescription label shall comply with all related USP chapter requirements as well as the labeling requirements as set forth in Article XIV of these regulations.
- D. A pharmacy may compound drugs prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/practitioner relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy as required by the Mississippi Board of Pharmacy.
- E. Pharmacies shall not offer compounded human drug products to practitioners or to other pharmacies for resale or dispensing. However, patient specific medications may be prepared on behalf of a pharmacy permitted as an Institutional I, Hospital, 3.1 pharmacy for an inpatient at that facility. Pharmacies may compound patient specific medications for office administration by a practitioner.
- F. Compounding pharmacies may advertise or otherwise promote the fact that they provide prescription compounding services (e.g., chemicals, devices and information when requested); however, they shall not solicit business by promoting to compound specific drug products (e.g., like a manufacturer).
- G. The compounding of inordinate amounts of drugs in anticipation of receiving prescriptions without any historical basis or the distribution of inordinate amounts of compounded products without a patient/practitioner/pharmacist relationship is considered manufacturing.

RECORDS

- A. The pharmacy shall keep records of all compounded products as required by the Mississippi Board of Pharmacy. Such records shall be readily available for authorized inspection during the retention period at the establishment. These records shall be subject to duplication by photocopying or other means of reproduction as part of any such inspection.
- B. Drug Orders: The pharmacist must receive a written, electronic or verbal order from an authorized prescriber before dispensing any compounded product.
 - If the drug order is for an inpatient at an institutional facility, a copy of the
 patient's medication order may serve as an order for the preparation and
 dispensing of the compounded product. This and the medication administration
 record may be maintained as the permanent record in medical records at the
 facility.
 - ii. If the drug order is for an outpatient, the order must be in the form of a prescription document or a patient medication order sheet which contains, at a minimum, the following:
 - (1) Patient name;
 - (2) Patient address;
 - (3) name of medication and strength;

- (4) Directions for use;
- (5) Date:
- (6) Prescriber's name;
- (7) Physician's address and Drug Enforcement Administration registration number, if applicable;
- (8) Refill instructions.
- C. Prescriptions for compounded products shall be filed in accordance with the prescription recordkeeping provisions of these regulations. Patient medication order sheets used as authorization for the dispensing of drugs shall be filed in an easily retrievable manner.

3. COMPOUNDING WHEN COMMERCIAL PRODUCTS ARE NOT AVAILABLE

- A. A pharmacy may prepare a copy of a commercial product when that commercial product is not available as evidenced by either of the following:
 - i. Products that appear as unresolved status on the FDA drug shortage list in effect under section 506E of the FD&C Act; or
 - ii. Products discontinued and no longer marketed by the manufacturer-

4. COMPOUNDING FOR VETERINARY USE

- A. All compounding for non-human medications must follow USP 795/797/800 compounding standards.
- B. A pharmacy may compound a preparation intended for administration to an animal patient:
 - i. Pursuant to a patient specific prescription; or
 - ii. Pursuant to a non-patient specific order from a veterinarian.
- C. The label for non-patient specific compounded preparations shall contain, at a minimum, the following:
 - i. Pharmacy's name, address and telephone number;
 - ii. Veterinarian's name:
 - iii. Name of preparation;
 - iv. Strength and concentration;
 - v. Lot number;
 - vi. Beyond use date (BUD);
 - vii. Special storage requirements, if applicable;
 - viii. Name or initials of the pharmacist responsible for final check of the preparation.

TITLE 30: PROFESSIONS AND OCCUPATIONS

PART 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS

ARTICLE XXXI COMPOUNDING GUIDELINES

Every pharmacy permitted by the Mississippi Board of Pharmacy engaged in the compounding of pharmaceuticals that is not a licensed 503B pharmacy following good manufacturing practices (GMP) shall comply with USP 797 and 795 standards 795, USP 797, and USP 800 when compounding in the scope of those chapters. The designated facility USP representative must be a pharmacist licensed in the State of Mississippi.

1. GENERAL PROVISIONS

- A. Prior to engaging in the compounding of pharmaceuticals, a pharmacy shall obtain a compounding certificate from the Mississippi Board of Pharmacy.
 - To obtain a compounding certificate, an applicant must complete a compounding certificate application.
 - ii. A compounding certificate will expire when the pharmacy permit expires and can be renewed at the time a pharmacy permit is renewed.
- iii. Compounding, without obtaining the compounding certificate, shall be grounds for disciplinary action.
- iv. Every pharmacy that engages in compounding shall submit a compounding statistical report to the Board on or about January 31st of each year on a form prescribed by the Board.
- Failure to submit the report as required by this regulation shall be grounds for disciplinary action.
- vi. A compounding certificate shall become inactive if a pharmacy fails to compound any prescriptions in a calendar year. A pharmacy may not compound prescriptions with an inactive compounding certificate. A pharmacy may petition the Board to activate a compounding certificate that is inactive.
- vii. Any pharmacy with an active compounding certificate is subject to a compounding inspection by the Board.
- B. Based on the existence of a pharmacist/patient/practitioner relationship and the presentation of a valid prescription, or in anticipation of prescription medication orders based on routine, regularly observed prescribing patterns, a pharmacy may compound, for an individual patient, medications that are not commercially available in the marketplace. Compounding and manufacturing, as defined within the regulations, are not permitted in the same facility. A pharmacy may not Compound a Drug that appears on the FDA List of Drugs withdrawn or removed from the market for Safety Reasons or on the FDA List of Drug products that present demonstrable difficulties in compounding.
- C. For the purpose of this Article, <u>flavoring is not considered compounding</u>. In addition, the combining of commercially manufactured, ready- to-use products shall be exempt from USP 795 compounding standards under the following conditions:
 - No more than four (4) commercially manufactured ready-to-use products (that have not been manipulated) are used;
 - ii. Compounding is not done in anticipation of medication orders;
- iii. Must follow USP 795 beyond use dates (BUDs);

- iv. A valid prescription shall serve as the compounding record;
- v. The prescription label shall comply with <u>all related USP chapter requirements as</u>

 <u>well as</u> the labeling requirements as set forth in Article XIV of these regulations. <u>and also include:</u>
 - 1. Name of Preparation;
 - 2. Strength and concentration of each component;
 - 3. Beyond Use Date;
 - 4. Special storage requirements, if applicable; and
 - 5. Cautionary auxiliary labels, if applicable.
- D. A pharmacy may compound drugs prior to receiving a valid prescription based on a history of receiving valid prescriptions that have been generated solely within an established pharmacist/patient/practitioner relationship, and provided that they maintain the prescriptions on file for all such products compounded at the pharmacy as required by the Mississippi Board of Pharmacy.
- E. Pharmacies shall not offer compounded human drug products to practitioners or to other pharmacies for resale_or dispensing. However, patient specific medications may be prepared on behalf of a pharmacy permitted as an Institutional I, Hospital, 3.1 pharmacy for an inpatient at that facility. Pharmacies may compound patient specific medications for office administration by a practitioner.
- F. Compounding pharmacies may advertise or otherwise promote the fact that they provide prescription compounding services (e.g., chemicals, devices and information when requested); however, they shall not solicit business by promoting to compound specific drug products (e.g., like a manufacturer).
- G. The compounding of inordinate amounts of drugs in anticipation of receiving prescriptions without any historical basis or the distribution of inordinate amounts of compounded products without a patient/practitioner/pharmacist relationship is considered manufacturing.

2. RECORDS

- A. The pharmacy shall keep records of all compounded products as required by the Mississippi Board of Pharmacy. Such records shall be readily available for authorized inspection during the retention period at the establishment. These records shall be subject to duplication by photocopying or other means of reproduction as part of any such inspection.
- B. Drug Orders: The pharmacist must receive a written, electronic or verbal order from an authorized prescriber before dispensing any compounded product.
 - i.If the drug order is for an inpatient at an institutional facility, a copy of the patient's medication order may serve as an order for the preparation and dispensing of the compounded product. This and the medication administration record may be maintained as the permanent record in medical records at the facility.
- ii. If the drug order is for an outpatient, the order must be in the form of a prescription document or a patient medication order sheet which contains, at a minimum, the following:
 - 1. Patient name;
 - 2. Patient address:

- 3. name of medication and strength;
- 4. Directions for use;
- 5. Date:
- 6. Prescriber's name;
 - 7. Physician's address and Drug Enforcement Administration registration number, if applicable;
- 8. Refill instructions.
- C. Prescriptions for compounded products shall be filed in accordance with the prescription recordkeeping provisions of these regulations. Patient medication order sheets used as authorization for the dispensing of drugs shall be filed in an easily retrievable manner.

3. COMPOUNDING WHEN COMMERCIAL PRODUCTS ARE NOT AVAILABLE

- A. A pharmacy may prepare a copy of a commercial product when that commercial product is not available as evidenced by either of the following:
 - i. Products that appear <u>as unresolved status</u> on <u>the FDA drug shortage list in effect under section 506E of the FD&C Act a website maintained by the federal Food and Drug Administration (FDA) and/or the American Society of Health Systems Pharmacists (ASHP); or</u>
 - ii. Products temporarily unavailable discontinued and no longer marketed by from the manufacturer, as documented by invoice or other communication from the distributor or manufacturer.

4. COMPOUNDING FOR VETERINARY USE

- A. All compounding for non-human medications must follow USP 795/797/800 compounding standards.
- B. A pharmacy may compound a preparation intended for administration to an animal patient:
 - i. Pursuant to a patient specific prescription; or
 - ii. Pursuant to a non-patient specific order from a veterinarian.
 - C. The label for non-patient specific compounded preparations shall contain, at a minimum, the following:
 - i. Pharmacy's name, address and telephone number;
 - ii. Veterinarian's name:
 - iii. Name of preparation;
 - iv. Strength and concentration;
 - v. Lot number;
 - vi. Beyond use date (BUD);
- vii. Special storage requirements, if applicable;
- viii. Name or initials of the pharmacist responsible for final check of the preparation.

Title 30: Professions and Occupations

Part 3002: Mississippi Board of Pharmacy Administrative Rules

Part 3002 Chapter 1: Organization and Operation of the Board

Rule 1.1 Composition of the Board.

The State Board of Pharmacy shall consist of seven (7) appointed members. At least one (1) appointment shall be made from each of the five (5) congressional districts as they existed on July 1, 2001. Each appointed member of the Board shall be appointed by the Governor, with the advice and consent of the Senate, from a list of five (5) names submitted by the Mississippi Pharmacists Association with input from the Magnolia Pharmaceutical Society, the Mississippi Independent Pharmacies Association (MIPA). Mississippi Society of Health-System Pharmacists (MSHP) and Mississippi College of Clinical Pharmacy (MCCP) and other pharmacist associations or societies. Of the members appointed, one (1) shall, at the time of appointment, have had five (5) years' experience as a pharmacist at a facility holding an institutional permit, and one (1) shall, at the time of appointment, have had five (5) years' experience as a pharmacist at a facility holding a retail permit. Any person appointed to the Board shall be limited to two (2) full terms of office during any fifteen-year period. Members of the Board shall be appointed for terms of five (5) years from the expiration date of the previous terms. Any vacancy on the Board prior to the expiration of a term for any reason, including resignation, removal, disqualification, death or disability, shall be filled by appointment of the Governor for the balance of the unexpired term. The Mississippi Pharmacists Association with input from the Magnolia Pharmaceutical Society, the Mississippi Independent Pharmacies Association (MIPA). Mississippi Society of Health-System Pharmacists (MSHP) and Mississippi College of Clinical Pharmacy (MCCP) and other pharmacist associations or societies, shall submit a list of nominees no more than thirty (30) days after a vacancy occurs, and the Governor shall fill such vacancies within ninety (90) days after each such vacancy occurs. If an election is required to narrow the number of potential candidates for nominations to the Board, the Mississippi Pharmacists Association shall provide a ballot to each pharmacist holding a valid Mississippi license.

Source: Miss. Code Ann. § 73-21-75.

Rule 1.2 Qualifications of Board Members.

To be qualified to be a member of the Board, a person shall:

- A. Be an adult citizen of Mississippi for a period of at least five (5) years preceding his appointment to the Board;
- B. Be a pharmacist licensed and in good standing to practice pharmacy in the State of Mississippi; and
- C. Have actively engaged in the practice of pharmacy in Mississippi for a period of at least five (5) years.

The Governor may remove any or all members of the Board on proof of unprofessional conduct, continued absence from the state, or for failure to perform the duties of his office. Any member who shall not attend two (2) consecutive meetings of the Board for any reason other than illness of such member shall be subject to removal by the Governor. The president of the Board shall notify the Governor in writing when any such member has failed to attend two (2) consecutive regular meetings. No removal shall be made without first giving the accused an opportunity to be heard in refutation of the charges made against him, and he shall be entitled to receive a copy of the charges at the time of filing.

Source: Miss. Code Ann. § 73-21-75.

Rule 1.3 Oath, Meetings and Compensation of Board Members.

- A. Each person appointed as a member of the Board shall qualify by taking the oath prescribed by the Constitution for the state officers, and shall file certificate thereof in the office of the Secretary of State within fifteen (15) days after his appointment.
- B. There shall be a president of the Board and such other officers as deemed necessary by the Board elected by and from its membership.
- C. The Board shall meet at least once each quarter to transact business, and may meet at such additional times as it may deem necessary. Such additional meetings may be called by the president of the Board or a majority of the members of the Board.
- D. The place for each meeting shall be determined prior to giving notice of such meeting and shall not be changed after such notice is given without adequate subsequent notice.
- E. A majority of the members of the Board shall constitute a quorum for the conduct of the meeting and all actions of the Board shall be by a majority of the members present.
- F. Each member of the Board shall receive a per diem as provided in Mississippi Code Section 25-3-69, not to exceed thirty (30) days in any one (1) period of twelve (12) months, for each day actually engaged in meetings of the Board, together with necessary traveling and other expenses as provided in Mississippi Code Section 25-3-41.

Source: Miss. Code Ann. § 73-21-77.

Rule 1.4 Executive Director and Additional Employees.

- A. The Board shall employ an executive director of the Board. The executive director shall be a citizen of Mississippi and a pharmacist licensed and in good standing to practice pharmacy in the State of Mississippi, who has had five (5) years' experience as a pharmacist.
- B. The executive director shall receive a salary to be set by the Board, subject to the approval of the State Personnel Board, and shall be entitled to necessary expenses incurred in the performance of his official duties. He shall devote full time to the duties of his office and shall not be engaged in any other business that will interfere with the duties of his office.
- C. The duties and responsibilities of the executive director shall be defined by rules and regulations prescribed by the Board.
- D. The Board may, in its discretion, employ persons in addition to the executive director in such other positions or capacities as it deems necessary to the proper conduct of Board business. Any pharmacist-investigator employed by the Board may have other part-time employment, provided that he shall not accept any employment that would cause a conflict of interest in his pharmacist-investigator duties. The Board may employ legal counsel to assist in the conduct of its business.

Source: Miss. Code Ann. § 73-21-79.

Rule 1.5 General Powers and Duties of the Board.

The responsibility for the enforcement of the provisions of the Mississippi Pharmacy Practice Act shall be vested in the Board. The Board shall have all of the duties, powers and authority specifically granted by and necessary to the enforcement of the Mississippi Pharmacy Practice Act.

The Board may make, adopt, amend and repeal such rules and regulations as may be deemed necessary by the Board from time to time for the proper administration and enforcement of the Mississippi Pharmacy Practice Act, in accordance with the provisions of the Mississippi Administrative Procedures Law.

Source: Miss. Code Ann. § 73-21-81.

Rule 1.6 Regulation of the Practice of Pharmacy.

- A. The Board shall be responsible for the control and regulation of the practice of pharmacy, to include the regulation of pharmacy externs or interns and pharmacist technicians in this state, the regulation of the wholesaler distribution of drugs and devices as defined in Mississippi Code Section 73-21-73, and the distribution of sample drugs or devices by manufacturer's distributors as defined in Mississippi Code Section 73-21-73 by persons other than the original manufacturer or distributor in this state.
- B. A license for the practice of pharmacy shall be obtained by all persons prior to their engaging in the practice of pharmacy. However, the provisions of the Pharmacy Practice Act shall not apply to physicians, dentists, veterinarians, osteopaths or other practitioners of the healing arts who are licensed under the laws of the State of Mississippi and are authorized to dispense and administer prescription drugs in the course of their professional practice.
- C. The initial licensure fee shall be set by the Board but shall not exceed Two Hundred Dollars (\$200.00).
- D. All students actively enrolled in a professional school of pharmacy accredited by the American Council on Pharmaceutical Education who are making satisfactory progress toward graduation and who act as an extern or intern under the direct supervision of a pharmacist in a location permitted by the Board of Pharmacy must obtain a pharmacy student registration prior to engaging in said activity. The student registration fee shall be set by the Board but shall not exceed One Hundred Dollars (\$100.00).
- E. All persons licensed to practice pharmacy prior to July 1, 1991, by the State Board of Pharmacy under Mississippi Code Section 73-21-89 shall continue to be licensed under the provisions of Mississippi Code Section 73-21-91.

Source: Miss. Code Ann. § 73-21-83.

Rule 1.7 Public Information.

The public may obtain information regarding operations and responsibilities of the Mississippi Board of Pharmacy, the Pharmacy Practice Act, Board Regulations and other pertinent information by contacting the Board office at 6360 I-55 North, Suite 400, Jackson, Mississippi 39211-2038, or by phone at 601-605-5388. Additional information is also available on the Mississippi Board of Pharmacy website at www.mbp.state.ms.us.

Source: Miss. Code Ann. § 73-21-81.

Part 3002 Chapter 15: Oral Proceedings On Proposed Regulations

Rule 15.1 Application of Chapter.

This chapter applies to all oral proceedings held for the purpose of providing the public an opportunity to make oral presentations or written input on proposed new rules or regulations, amendments to rules or regulations and proposed repeal of existing rules or regulations before the Board pursuant to the

Administrative Procedures Act.

Source: Miss. Code Ann. § 25-43-2.104.

Rule 15.2 When Oral Proceedings will be Scheduled on Proposed Regulations.

The Board will conduct an oral proceeding on a proposed regulation or amendment if requested by a political subdivision, an agency or ten (10) persons in writing within twenty (20) days after the filing of the notice of the proposed regulation.

- A. Each request must be submitted on 8-1/2" x 11" white paper or electronically in a standard letter format, i.e., MS Word, PDF, WordPerfect or other similar format and must be typewritten or printed in legible handwriting.
- B. The request may be in the form of a letter addressed to the Board.
- C. Each request must include the full name, telephone numbers, and mailing address of the requestor(s).
- D. All requests shall be signed by the person filing the request, unless represented by an attorney, in which case the attorney may sign the request.

Source: Miss. Code Ann. §§ 25-43-2.104, 25-43-3.104

Rule 15.3 Notification of Oral Proceeding.

The date, time and place of all oral proceedings shall be filed with the Secretary of State's office and mailed to each requestor. The oral proceedings will be scheduled no earlier than twenty (20) days from the filing of this information with the Secretary of State.

Source: Miss. Code Ann. §§ 25-43-2.104, 25-43-3.104

Rule <u>1</u>5.4 Presiding Officer.

The Board President or his designee, who is familiar with the substance of the proposed regulation, shall preside at the oral proceeding on a proposed regulation.

Source: Miss. Code Ann. § 25-43-2.104

Rule <u>1</u>5.5 Public Presentations and Participation.

- A. At an oral proceeding on a proposed regulation, persons may make oral statements and make documentary and physical submissions, which may include data, views, comments or arguments concerning the proposed regulation.
- B. Persons wishing to make oral presentations at such a proceeding shall notify the Board at least one business day prior to the proceeding and indicate the general subject of their presentations. The presiding officer in his or her discretion may allow individuals to participate that have not previously contacted the Board.
- C. At the proceeding, those who participate shall indicate their names and addresses, identify any persons or organizations they may represent, and provide any other information relating to their participation deemed appropriate by the presiding officer.
- D. The presiding officer may place time limitations on individual oral presentations when necessary to assure the orderly and expeditious conduct of the oral proceeding. To encourage joint oral presentations and to avoid repetition, additional time may be provided for persons whose presentations represent the views of other individuals as well as their own views.
- E. Persons making oral presentations are encouraged to avoid restating matters that have already

been submitted in writing.

F. There shall be no interruption of a participant who has been given the floor by the presiding officer, except that the presiding officer may in his or her discretion interrupt or end the partisan's time where the orderly conduct of the proceeding so requires.

Source: Miss. Code Ann. § 25-43-2.104

Rule 15.6 Conduct of Oral Proceeding.

- A. The presiding officer shall have authority to conduct the proceeding in his or her discretion for the orderly conduct of the proceeding. The presiding officer shall:
 - 1. call proceeding to order;
 - give a brief synopsis of the proposed regulation, a statement of the statutory authority for the proposed regulation, and the reasons provided by the Board for the proposed regulation;
 - call on those individuals who have contacted the Board about speaking on or against the proposed regulation;
 - 4. allow for rebuttal statements following all participant's comments;
 - 5. adjourn the proceeding.
- B. The presiding officer, where time permits and to facilitate the exchange of information, may open the floor to questions or general discussion. The presiding officer may question participants and permit the questioning of participants by other participants about any matter relating to that regulation-making proceeding, including any prior written submissions made by those participants in that proceeding; but no participant shall be required to answer any question.
- C. Physical and Documentary Submissions presented by participants in an oral proceeding shall be submitted to the presiding officer. Such submissions become the property of the Board and are subject to the Board's public records request procedure.
- D. The Board may record oral proceedings by stenographic or electronic means.

Source: Miss. Code Ann. § 25-43-2.104

Part 3002 Chapter 26: Declaratory Opinions

Rule <u>26</u>.1 Application of Chapter.

This chapter sets forth the Board's rules governing the form, content, and filing of requests for declaratory opinions, the procedural rights of persons in relation to the written requests, and the Board's procedures regarding the disposition of requests as required by Mississippi Code § 25- 43-2.103.

Source: Miss. Code Ann. § 25-43-2.104

Rule <u>26.2</u> Scope of Declaratory Opinions.

The Board will issue declaratory opinions regarding the applicability to specified facts of:

- A. a statute administered or enforceable by the Board;
- B. a rule or regulation promulgated by the Board, or
- C. an order issued by the Board.

Source: Miss. Code Ann. § 25-43-2.104.

Rule <u>26</u>.3 Scope of Declaratory Opinion Request.

A declaratory opinion request must be limited to a single transaction, occurrence or issue.

Source: Miss. Code Ann. § 25-43-2.104.

Rule 26.4 Persons Who May Request Declaratory Opinions.

Any person with a substantial interest in the subject matter may request a declaratory opinion from the Board. "Substantial interest in the subject matter" means: an individual, business, group or other entity that is directly affected by the Board's administration of the laws within its primary jurisdiction. "Primary jurisdiction of the Board" means the Board has a constitutional or statutory grant of authority in the subject matter at issue.

Source: Miss. Code Ann. §§ 25-43-2.103, 25-43-2.104.

Rule 26.5 How to Submit Requests for Declaratory Opinions.

When a person with substantial interest, as required by Section 25-43-2.103 of the Administrative Procedures Act, requests a declaratory opinion, the person must submit a printed, typewritten, or legibly handwritten request.

- A. Each request must be submitted on 8-1/2" x 11" white paper or electronically in a standard letter format, i.e., MS Word, PDF, WordPerfect or other similar format.
- B. The request may be in the form of a letter addressed to the Board or in the form of a pleading as if filed with a court.
- C. Each request must include the full name, telephone numbers, and mailing address of the requestor(s).
- D. All requests shall be signed by the person filing the request, unless represented by an attorney, in which case the attorney may sign the request.
- E. Each request must clearly state that it is a request for a declaratory opinion.
- F. All requests must be mailed, emailed, delivered or transmitted via facsimile to the Board. No oral or telephone requests will be accepted for official declaratory opinions.

Source: Miss. Code Ann. § 25-43-2.104.

Rule 26.6 Signature Attestation.

Any party who signs the request shall attest that the request complies with the requirements set forth in these rules, including but not limited to a full, complete, and accurate statement of relevant facts and that there are no related proceedings pending before any agency, administrative, or judicial tribunal.

Source: Miss. Code Ann. § 25-43-2.104.

Rule <u>26</u>.7 Content of Request.

Each request must contain the following:

- A. A clear identification of the statute, rule, or order at issue;
- B. The question for the declaratory opinion;
- C. A clear and concise statement of all facts relevant to the question presented:
- D. The identity of all other known persons involved in or impacted by the facts giving rise to the request including their relationship to the facts, and their name, mailing address, and telephone number:
- E. A statement sufficient to show that the requestor has a substantial interest in the subject matter of the request;

F. A suggested proposed opinion, stating the answers desired by requestor and a summary of the reasons in support of those answers;

Source: Miss. Code Ann. §§ 25-43-2.103, 25-43-2.104.

Rule 26.8 Reasons for Refusal to Issue a Declaratory Opinion Upon a Request.

The Board may, for good cause, refuse to issue a declaratory opinion. The circumstances in which declaratory opinions will not be issued include, but are not necessarily limited to:

- A. The matter is outside the primary jurisdiction of the Board;
- B. Lack of clarity concerning the question presented;
- C. There is pending or anticipated litigation, administrative action, or other adjudication which may either answer the question presented by the request or otherwise make an answer unnecessary;
- D. The statute, rule, or order on which a declaratory opinion is sought is clear and not in need of interpretation to answer the question presented by the request;
- E. The facts presented in the request are not sufficient to answer the question presented;
- F. The request fails to contain information required by these rules or the requestor failed to follow the procedure set forth in these rules;
- G. The request seeks to resolve issues which have become moot or are abstract or hypothetical such that the requestor is not substantially affected by the rule, statute, or order on which a declaratory opinion is sought;
- H. No controversy exists or is certain to arise which raises a question concerning the application of the statute, rule, or order;
- I. The question presented by the request concerns the legal validity of a statute, rule, or order;
- J. The request is not based upon facts calculated to aid in the planning of future conduct, but is, instead, based on past conduct in an effort to establish the effect of that conduct;
- K. No clear answer is determinable:
- L. The question presented by the request involves the application of a criminal statute or sets forth facts which may constitute a crime;
- M. The answer to the question presented would require the disclosure of information which is privileged or otherwise protected by law from disclosure;
- N. The question is currently the subject of an Attorney General's opinion request or has been answered by an Attorney General's opinion;
- O. A similar request is pending before this agency, or any other agency, or a proceeding is pending on the same subject matter before any agency, administrative or judicial tribunal, or where such an opinion would constitute the unauthorized practice of law; or
- P. The question involves eligibility for a license, permit, certificate or other approval by the Board or some other agency and there is a statutory or regulatory application process by which eligibility for said license, permit, or certificate or other approval may be determined.

Source: Miss. Code Ann. §§ 25-43-2.103, 25-43-2.104.

Rule 26.9 Agency Response.

Within forty-five (45) days after the receipt of a request for a declaratory opinion which complies with the requirements of these rules, the Board shall, in writing:

- A. Issue an opinion declaring the applicability of the statute, rule, or order to the specified circumstances;
- B. Agree to issue a declaratory opinion by a specified time but no later than ninety (90) days after receipt of the written request; or

C. Decline to issue a declaratory opinion, stating the reasons for its action.

The forty-five (45) day period shall begin on the first business day after which the request is received by the Board.

Source: Miss. Code Ann. §§ 25-43-2.103, 25-43-2.104.

Rule 26.10 Availability of Declaratory Opinions and Requests for Opinions.

Declaratory opinions and requests for declaratory opinions shall be available for public inspection and copying in accordance with the Public Records Act and the Board's public records request procedure. All declaratory opinions and requests shall be indexed by requestor's name, subject and date of issuance. Declaratory opinions and requests which contain information which is confidential or exempt from disclosure under the Mississippi Public Records Act or other laws shall be exempt from this requirement and shall remain confidential.

Source: Miss. Code Ann. §§ 25-43-2.103, 25-43-2.104.

Rule 26.11 Notice by Board to third parties.

The Board may give notice to any person, agency or entity that a declaratory opinion has been requested and may receive and consider data, facts, arguments and opinions from other persons, agencies or other entities other than the requestor.

Source: Miss. Code Ann. § 25-43-2.104.

Rule 26.12 Effect of a Declaratory Opinion.

The Board will not pursue any civil, criminal or administrative action against a person who is issued a declaratory opinion from the Board and who, in good faith, follows the direction of the opinion and acts in accordance therewith unless a court of competent jurisdiction holds that the opinion is manifestly wrong. Any declaratory opinion rendered by the Board shall be binding only on the Board and the person to whom the opinion is issued. No declaratory opinion will be used as precedent for any other transaction or occurrence beyond that set forth by the requesting person.

Source: Miss. Code Ann. §§ 25-43-2.103, 25-43-2.104.

Part 3002 Chapter 37: Public Records

Rule <u>3</u>7.1 Public Record Requests Procedures.

This rule establishes procedures and fees associated with all public requests for copies and/or inspection of public documents.

- A. Submission of Requests.
 - All requests for information should be submitted to the Mississippi Board of Pharmacy either in writing or via email.
 - 2. No verbal or telephone requests can be accepted.
 - 3. The request should specifically outline the records that are being requested.
- B. Timetable for processing.

All document requests will be approved or denied within seven (7) business days after the request is received. In the event of a denial for all or part of the request, the Board will provide an explanation of the denial to the requestor in writing. If the requested information is unable to be

produced by the seventh day after the request is made, the Board will provide a written explanation regarding why the document cannot be produced during that timeframe. Unless there is a mutual agreement of the parties, in no case shall the production of the requested records, after timely payment and unless otherwise exempt, be any later than fourteen (14) working days from the receipt of the request.

C. Exempt Documents.

Some documents are exempt from publication such as personnel records, attorney communications and work products of attorneys.

D. Third Party Information.

Records furnished to the Board by third parties which contain trade secrets or confidential commercial or financial information shall not be subject to inspection, examination, copying or reproduction until the third party has been advised that the documents will be released. Further, no third-party information will be released if a third party obtains a court order prohibiting the same. The requestor will be notified of any court orders that prohibit the release of the requested information.

E. Assessment of costs to the Requestor.

Payment for information requested must be made in advance of receipt of documents and must be sufficient to cover the actual costs for the Board to furnish the information. Such costs include, but are not limited to, staff time: to evaluate the request, to retrieve any relevant files, to organize the information, to notify any Third Parties, to develop a cost estimate and schedule, to reproduce the material, and to the deliver the information requested.

- 1. No cash, credit or debit cards, or personal checks can be accepted. Money orders, certified checks, or corporate checks are accepted.
- 2. An estimated cost will be provided to the requestor based on the volume of information, the format in which the information is stored and requested, and whether or not third-party information has been requested. The requestor may submit payment for processing of the request, amend the request or withdraw the request. The requestor should submit written notice of his/her intent to either proceed or withdraw the request.
- 3. If no response is given by the requestor within thirty (30) days of the estimated cost notification being sent, the Board will proceed no further with the request. If at a later date, the requestor decides to proceed with the request, he/she should submit a new request.
- 4. Timely payment under paragraph B. means payment received by the next business day after the estimated cost notification is provided to the requestor. By delaying the payment of the estimated fee past the next business day, the requestor acknowledges there may be a delay in the delivery of the requested documents. No request will be processed until payment is received.
- 5. The decision to charge for public records is at the discretion of the Board.
- F. Requests for Document Inspections.

The requestor will be billed for the total amount of time expended by employees of the Board assisting with the inspection of documents. Additional fees incident to document production may be assessed.

G. Public Information via the Internet.

Some information pertaining to the Mississippi Board of Pharmacy is available free of charge on the internet at www.mbp.state.ms.us.

Source: Miss. Code Ann. §§ 25-61-1 et seq., 73-21-81

Rule 37.2 Licensure Applications Exempt from Public Access.

All applications for licensure in the possession of the Board are exempt from the provisions of the Mississippi Public Records Act of 1983 <u>pursuant to Mississippi Code Annotated Section 73-52-1</u>.

Source: Miss. Code Ann. § 73-52-1.

Part 3002 Chapter 48: Background Checks

Rule <u>48</u>.1 Background Check Procedures.

The Board shall conduct background checks on any individual who applies for a license, registration or permit as required by law. Background checks shall include, but not be limited to, a criminal history records check requiring the applicant to be fingerprinted.

Source: Miss. Code Ann. §§ 73-21-81, 73-21-85, 73-21-111, 73-21-126.

Rule 48.2 Petition for Determination.

An individual may petition the Board for a determination of whether the individual's criminal record will disqualify the individual from obtaining a license, registration or permit. The determination petition shall be filed on a form supplied by the Board and accompanied by a fee of Twenty-Five Dollars (\$25.00).

Source: Miss. Code Ann. § 73-77-9.

Rule 48.3 Determination Factors.

The following factors shall be used to determine if an applicant with a disqualifying criminal conviction will be denied a license:

- A. The nature and seriousness of the crime for which the individual was convicted;
- B. The passage of time since the commission of the crime;
- C. The relationship of the crime to the ability, capacity, and fitness required to perform the duties and discharge the responsibilities of the occupation; and
- D. Any evidence of rehabilitation or treatment undertaken by the individual that might mitigate against a direct relation.

Source: Miss. Code Ann. § 73-77-7.

Rule 48.4 Disqualifying Determination Notification

If the Board denies an individual a license, registration or permit solely or in part because of the individual's prior conviction of a crime, the Board shall notify the individual in writing of the following:

- A. The grounds and reasons for the denial or disqualification;
- B. That the individual has the right to a hearing to challenge the Board's decision;
- C. The earliest date the person may reapply for a license, registration or permit; and
- D. That the evidence of rehabilitation may be considered upon reapplication.

Source: Miss. Code Ann. § 73-77-9.

Rule 48.5 Disqualifying Crimes

An individual may be denied a license, registration or permit based on a conviction, guilty plea and/or a plea of nolo contender to a felony, which includes, but is not limited to, any of the following:

A. Any controlled substance violation;

- B. Embezzlement
- C. Shoplifting
- D. Theft
- E. Forgery
- F. Burglary
- G. Identity theft

In addition, the accumulation of multiple convictions, including misdemeanor convictions, and pending unresolved charges may be used to determine if an individual shall be denied a license, registration or permit.

Source: Miss. Code Ann. § 73-21-81.

Rule 48.6 Mitigating Factors

Notwithstanding Rule 48.5, any criminal conviction beyond ten (10) years prior to the application shall not disqualify an individual unless extenuating circumstances exist. Those extenuating circumstances shall be enumerated in the disqualifying determination notification. Other mitigating factors to be considered in determining whether the individual's criminal record will disqualify the individual from obtaining a license, registration or permit may include, but need not be limited to:

- A. age at which the crime was committed;
- B. circumstances surrounding the crime;
- C. length of time since the conviction and criminal history since the conviction;
- D. work history;
- E. current employment and character references; and
- F. other evidence demonstrating the ability of the person to perform the employment responsibilities competently and that the person does not pose a threat to the health or safety of the public.

Source: Miss. Code Ann. § 73-21-81.

Part 3002 Chapter 52: Disciplinary Actions

Rule <u>52</u>.1 Grounds for Disciplinary Actions.

- A. The Board may refuse to issue or renew, or may suspend, reprimand, revoke or restrict the license, registration or permit of any person upon one or more of the <u>provisions listed in Mississippi Code Annotated Section 73-21-97.following grounds:</u>
- <u>B.</u> Unprofessional conduct. Unprofessional conduct shall include, but not be limited to:
 - 1. The publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy;
 - 2 Attempting to circumvent the patient counseling requirements, or discouraging the patient from receiving patient counseling concerning their prescription drug orders;
 - 3. The illegal use or disclosure of Protected Health Information (PHI) or other confidential patient information; failure to maintain adequate records, systems, and security to protect against the illegal use or disclosure of PHI or other confidential patient information; or failure to maintain adequate records to account for disclosures of PHI;
 - Dispensing, selling, bartering, receiving or maintaining drugs or devices which is known or should have been known to have been stolen or diverted from the purpose for which they were distributed by a legitimate source;
 - 5. Engaging in conduct likely to deceive, defraud, or harm the public, or demonstrating a

- willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from the standards of care ordinarily exercised by a pharmacist, with proof of actual injury not having to be established;
- 6. Selling a drug for which a prescription drug order from a practitioner is required, without having received a <u>valid</u> prescription drug order for the drug;
- Failing to maintain complete and accurate records of all drugs received, dispensed, or disposed of in compliance with the Federal laws and regulations and State laws, rules and regulations;
- 8. Failure to report fraudulent prescription activity to the Board or other appropriate authorities;
- 9. Obtaining any remuneration by fraud, misrepresentation, or deception, including, but not limited to, receiving remuneration for amending or modifying, or attempting to amend or modify, a patient's pharmacist care services, absent a clear benefit to the patient., solely in response to promotion or marketing activities;
- 10. Filing a claim or assisting in the filing of a claim for reimbursement for drugs or professional services which were not provided, or which were not authorized to be provided.
- C. Physical or mental incapacity of a nature that prevents a pharmacist, a pharmacy intern/extern, or a pharmacy technician from engaging in the practice of pharmacy or assisting in the practice of pharmacy with reasonable skill, confidence and safety to the public;
- D. Being found guilty by a court of competent jurisdiction of one or more of the following:
 - 1. A felony;
 - 2. Any act involving moral turpitude or gross immorality; or
 - 3. Violation of pharmacy or drug laws of this state or rules and regulations pertaining thereto, or of statutes, rules or regulations of any other state or the federal government;
- <u>E.</u> Fraud or intentional misrepresentation by a licensee, registrant or permit holder in securing the issuance or renewal of a license, registration or permit;
- <u>F.</u> Engaging or aiding and abetting an individual to engage in the practice of pharmacy without a license;
- <u>F.</u> Violation of any of the provisions of the Mississippi Pharmacy Practice Act or rules or regulations adopted pursuant to such Act; or <u>V</u>violation of pharmacy or drug laws of any other state or the federal government or the rules/regulations pertaining thereto;
- G. Violation of any of the provisions of the Mississippi Uniform Controlled Substances Law;
- H. Failure to comply with lawful orders of the Board;
- I. Negligently or willfully acting in a manner inconsistent with the health or safety of the public;
- J. Addiction to or dependence on alcohol, controlled substances or other habit forming legend drugs or the unauthorized use, possession or theft of controlled substances or other habit forming legend drugs;
- **K.** Misappropriation of any prescription drug;
- <u>L.</u> Being found guilty by the licensing agency in another state or the federal government of violating the statutes, rules or regulations of that jurisdiction;
- M. The unlawful or unauthorized possession or use of a controlled substance;
- <u>H.</u> Failure to immediately report directly to the Board, losses or suspected losses of controlled substances or prescription drugs;
- <u>I.</u> Theft or embezzlement of prescription drugs, controlled substances, medical devices, or anything of value from a permitted facility;
- <u>J.</u> Termination of employees suspected of theft of pharmaceuticals, or merchandise or anything of value without contacting the Board prior to termination;
- <u>K.</u> Failure of a pharmacist licensed by the Mississippi Board of Pharmacy to register as a user of the Prescription Monitoring Program (PMP); Willful failure to submit drug monitoring information

- or willful submission of incorrect dispensing information as required by the Prescription Monitoring Program under Mississippi Code Section 73-21-127;
- <u>L.</u> <u>T</u>the unlawful disclosure of information from the PMP or using information obtained from the PMP for unlawful or unethical purposes;
- R. Failure to obtain the license, registration or permit required by this Mississippi Pharmacy Practice Act;
- <u>S.</u> Violation(s) of the provisions of Mississippi Code Sections 41-121-1 through 41-121-9 relating to deceptive advertisement by health care practitioners;
- M. Receiving, dispensing, selling, bartering or maintaining a prescription drug sample unless the pharmacy is owned by a charitable organization and is not operated for profit and has prior approval in writing by the Board. Institutional pharmacies may receive, dispense and maintain prescription drug samples that are provided by a practitioner and intended solely for administration to his/her patients confined to the institution provided no charge is made to the patient by the institution for the sample;
- No pharmacist shall have possession of a prescription drug sample unless such sample is for treatment of a diagnosed personal medical condition;
- O. Jeopardizing, compromising, interfering or failing to cooperate with any lawful investigation conducted by the Board or any state or federal regulatory or law enforcement agency;
- <u>P.</u> Failure to furnish the Board, its agents or representatives any information legally requested by the Board, or retaliation against pharmacy employees for providing information to the Board;
- Q. Destruction, removal or tampering with any prescription drug, controlled substance, or medical device placed under seal, embargoed, or quarantined by the Board or any representative of the Board;
- <u>R.</u> Any act by any person which subverts the authority of the pharmacist-in-charge by impeding the management of the prescription department or the practice of pharmacy in the compliance with federal and state drug or pharmacy laws and regulations;
- S. Retaliation against a pharmacist for practicing or attempting to practice pharmacy in compliance with federal and state drug or pharmacy laws and regulations;
- T. Failure to produce evidence of continuing educations credits as required by regulation.

Source: Miss. Code Ann. §§ 73-21-81, 73-21-97

Rule 2.2 Alternative to Suspension, Revocation or Restriction of a License.

In lieu or suspension, revocation or restriction of a license as provided in Rule 2.1, the Board may warn or reprimand the offending pharmacist.

Source: Miss. Code Ann. § 73-21-97.

Rule 2.3 Additional Grounds for Discipline.

In addition to the grounds specified in Rule 2.1, the Board shall be authorized to suspend the license, registration or permit of any person for being out of compliance with an order for support, as defined in Mississippi Code Section 93-11-153. The procedure for suspension of a license, registration or permit for being out of compliance with an order for support, and the procedure for reissuance or reinstatement of a license, registration or permit suspended for that purpose, and the payment of any fees for the reissuance or reinstatement of a license, registration or permit suspended for that purpose, shall be governed by Mississippi Code Section 93-11-157 or 93-11-163, as the case may be. If there is any conflict between any provision of Mississippi Code Section 93-11-157 or 93-11-163 and the provisions of the Mississippi Pharmacy Board Rules and Regulations, the provisions of Mississippi Code Section

93-11-157 or 93-11-163, as the case may be, shall control.

Source: Miss. Code Ann. § 73-21-97.

Rule 2.4 Investigations Review Committee.

The Board shall designate two (2) of its members to serve on a rotating no longer than three consecutive month basis with the executive director and legal counsel for the Board as an Investigations Review Committee (IRC).

Source: Miss. Code Ann. § 73-21-99.

Rule 2.5 Meetings of the Investigations Review Committee.

The IRC shall meet monthly and the Board's investigators shall provide status reports to the IRC. Such reports shall be made on all on-going investigations, and shall apply to any routine inspections which may give rise to the filing of a complaint.

Source: Miss. Code Ann. § 73-21-99.

Rule 2.6 Actions of the Investigations Review Committee.

The Board, acting by and through the IRC may, if deemed necessary, issue a letter of reprimand to any licensee, registrant or permit holder in lieu of formal action by the Board.

Source: Miss. Code Ann. § 73-21-99.

Part 3002 Chapter 63: Disciplinary Proceedings

Rule <u>6</u>3.1 Disciplinary Resolutions.

All disciplinary proceedings initiated by the Board shall be brought to a final resolution through one of the following means:

- A. Formal Disciplinary hearing before the Board;
- B. Acceptance by the Board of a mutually agreeable SettlementConsent Order in lieu of a hearing;
- C. Issuance of an Administrative Citation by the Investigations Review Committee (IRC) and payment of a fine by the Respondent in lieu of a hearing; or
- D. Dismissal of the case.

Source: Miss. Code Ann. § 73-21-81.

Rule 3.2 Formal Disciplinary Hearing.

Disciplinary action by the Board against a licensee, registrant or permit holder, or license, registration or permit shall require the following:

- A. A sworn affidavit filed with the Board charging a licensee or permit holder with an act which is grounds for disciplinary action; and
- B. An order of the IRC which shall cause the executive director of the Board to fix a time and place for a hearing by the Board. The executive director shall cause a written notice specifying the offense or offenses for which the licensee or permit holder is charged and notice of the time and place of the hearing to be served upon the licensee or permit holder at least thirty (30) days prior to the hearing date. Such notice may be served by mailing a copy by certified mail, postage prepaid, to the last known residence or business address of the licensee or permit holder.

Source: Miss. Code Ann. § 73-21-99.

Rule 3.3 Recusal of IRC Members from Board Action.

In the event any complaint on a licensee comes before the Board for possible disciplinary action, the members of the Board serving on the IRC which reviewed the investigation of that complaint shall recuse themselves and not participate in the disciplinary proceeding.

Source: Miss. Code Ann. § 73-21-99.

Rule 6.23.4 Issuance of Subpoenas.

The Board, acting by and through its executive director, is authorized and empowered to issue subpoenas for the attendance of witnesses and the production of books and papers at a hearing. Process issued by the Board shall extend to all parts of the state and shall be served by any person designated by the Board for such service. Where any witness fails or refuses to attend upon a subpoena issued by the Board, refuses to testify, or refuses to produce any books and papers the production of which is called for by a subpoena, the attendance of such witness, the giving of his testimony or the production of the books and papers shall be enforced by any court of competent jurisdiction of this state in the manner provided for the enforcement of attendance and testimony of witnesses in civil cases in the courts of this state.

- A. All requests for subpoenas shall be submitted at least fifteen (15) days prior to the scheduled hearing.
- B. The request must contain the identity and address of the individual to be subpoenaed.
- C. If the subpoena is for records or documents, the request must include the identity and address of the custodian of such records, along with a concise description of the records to be subpoenaed.
- D. The Board will general serve all subpoenas by registered mail, return receipt requested or by hand delivery.
- E. The Board shall charge a reasonable fee for each subpoena, not to exceed thirty-five dollars (\$35.00), for preparation and service of each subpoena.

Source: Miss. Code Ann. §§ 73-21-99, 73-21-81.

Rule 3.5 Rights of the Accused.

The accused shall have the right to appear at a disciplinary hearing either personally or by counsel, or both, to produce witnesses or evidence in his behalf, to cross-examine witnesses, and to have subpoenas issued by the Board.

Source: Miss. Code Ann. § 73-21-99.

Rule 6.33.7 Prehearing Motions.

All <u>prehearing</u> motions must be filed with the Board at least fifteen (15) days prior to the scheduled hearing. The Board President shall have the authority to rule on motions that are filed pursuant to this Rule. The Respondent and the Board counsel will be notified of the ruling on the motion promptly. The ruling of the Board President will be entered into the record at the scheduled hearing date. Motions for continuances shall be handled pursuant to Rule <u>6.43.8</u>.

Source: Miss. Code Ann. § 73-21-81.

Rule 6.43.8 Hearing Continuances.

A motion for continuance must be filed with the Board at least fifteen (15) days prior to the scheduled hearing, or upon a showing of good cause, at any time prior to the hearing. A scheduling conflict on behalf of the Respondent or Respondent's counsel shall be considered good cause, and will be liberally granted, if written proof of the scheduling conflict is submitted to the Board at least fifteen (15) days prior to the scheduled hearing. A second continuance based on scheduling conflicts shall not be granted by the Board. Failure to retain counsel in a timely manner on the part of the Respondent shall not be considered good cause. The Board President or Executive Director shall have the authority to rule on motions for continuance that are filed pursuant to this Rule. The Respondent and the Board counsel will be notified of the ruling on the motion promptly. The ruling of the Board President or Executive Director will be entered into the record at the scheduled hearing date and the rescheduled hearing date will be set if the motion for continuance is granted.

Source: Miss. Code Ann. § 73-21-81.

Rule 6.53.6 Hearing Procedures.

- A. All hearings shall be conducted by the Board, which shall not be bound by strict rules of procedure or by the laws of evidence in the conduct of its proceedings.
- B. The hearing shall be held at the time and place as specified in the Notice of Hearing and Complaint unless continued for good cause.
- C. All hearings are open to the public, subject to the Board entering executive session, which shall be closed to the public.
- D. The Board President, Vice-President or senior member of the Board will preside over the hearing.
- E. The Board may be assisted by a hearing officer who shall advise the Board on matters of law and procedure and rule on all objections and motions. The hearing officer's rulings on matters of law and procedure are advisory.
- F. Any Board members that participated in the IRC for the matter before the Board will recuse themselves and not participate in the hearing.
- G. All hearings shall be recorded and the Board, or court reporter, shall administer oaths as may be necessary for the proper conduct of the hearing.
- H. The Respondent may retain legal counsel or may represent themselves.
- I. Upon direction from the Presiding Officer, the Board counsel shall present evidence and call witnesses to support the charges filed in the Notice of Hearing and Complaint.
- J. The Respondent or Respondent's counsel may present evidence or call witnesses to answer the charges filed in the Notice of Hearing and Complaint.
- K. The Board shall not hear evidence nor make findings on any violations that were not part of the Notice of Hearing and Complaint.
- L. All witnesses at the hearing shall be subject to direct examination, cross examination and questions by the Board. Re-direct and re-cross examinations shall be at the discretion of the Board.
- M. The Board should adjudicate each charge and make findings of fact on each charge as presented in the Notice of Hearing and Complaint. Any determination by the Board shall be based upon sufficient evidence to sustain it.
- N. The Board shall, within thirty (30) days after the conclusion of the hearing, reduce its decision

to writing and forward an attested true copy to the last-known residence or business address of the licensee or permit holder by way of United States first-class, certified mail, postage prepaid.

Source: Miss. Code Ann. §§ 73-21-99; 73-21-81.

Rule 6.63.9 Settlement Negotiations and Agreed Settlement Orders.

When the Respondent has been duly served with a Notice of Hearing and Complaint, the Respondent and/or Respondent's counsel may request Settlement negotiations for the purpose of possible resolution of the matter or for purpose of simplifying the issues for hearing or promoting stipulations as to facts and proposed evidentiary offerings which will not be disputed at hearing.

- A. The Respondent and/or his counsel and Board Counsel shall participate in the settlement negotiations. Board members who served on the Investigations Review Committee (IRC) for the matter and compliance agents who investigated the matter shall be consulted during the settlement negotiations. Other Board members may not participate nor have knowledge or input into any of the settlement negotiations.
- B. Informal Discovery or exchange of information may be accomplished during the settlement negotiations.
- C. Settlement Conferences shall not be held on the day of the scheduled hearing.
- D. The settlement negotiations may result in:
 - a. Preparation of a proposed Agreed Order as a resolution of the matter; or
 - b. Proceeding with the scheduled hearing.
- C. Any action which the Board may take following a full disciplinary hearing may be taken by Agreed Settlement Order.
- D. Any proposed Agreed Settlement Order must be approved by both Board members who served on the Investigations Review Committee (IRC) for the matter. The proposed Agreed Settlement Order shall be presented to the Board at the scheduled Hearing date and time. The terms of the Agreed Settlement Order are not effective until approved by the Board.
- E. The Respondent has the obligation to personally appear before the Board on the scheduled hearing date to answer any questions which the Board may have prior to approving the proposed Agreed Settlement Order.
- F. Failure of the Board to approve the proposed Agreed <u>Settlement Order</u> shall result in a formal disciplinary hearing before the Board on a rescheduled hearing date.

Source: Miss. Code Ann. § 73-21-81.

Rule 6.73.10 Administrative Citations.

The IRC may include an Administrative Citation with the Notice of Hearing and Complaint. In lieu of a formal disciplinary hearing, the Respondent has the option to settle the matter through the payment of a fine and compliance with imposed conditions. If the Respondent does not accept the fine and conditions or respond to the Administrative Citation instructions within the time specified in the Notice, the matter shall proceed to a formal disciplinary hearing before the Board.

Source: Miss. Code Ann. § 73-21-81.

Rule 3.11 Violations Subject to Administrative Citations and Fines.

An Administrative Citation may be issued for the following violations:

Failure of a Pharmacy Technician to wear a name tag identifying the individual as a Pharmacy

Technician

Failure to validate that a Pharmacy Technician has a current active registration

Exceeding the Pharmacist to Pharmacy Technician ratio

Failure to obtain the required Continuing Education

Failure to notify the Board of a change of employment

Failure to notify the Board of a change of address

Failure to notify the Board of a change in the Pharmacist in Charge (PIC)

Failure to obtain or renew a pharmacy permit in a timely manner

Failure to obtain or renew a pharmacist license in a timely manner

Failure to obtain or renew a control substance registration in a timely manner

Failure to Register as a Wholesaler

Any other violation of the Mississippi Pharmacy Practice Act or the Rules or Regulations of the Mississippi Pharmacy Board

The administrative citation may include a fine and cost of investigation for each violation, not to exceed the monetary penalty amount as allowed by Mississippi Code Annotated § 73-21-103 or other applicable statute.

Source: Miss. Code Ann. §§ 73-21-81, 73-21-103.

Rule 6.83.12 Additional Conditions for Administrative Citations.

In addition to any fine imposed, an Administrative Citation may include corrective action or additional conditions imposed by the IRC through a Memorandum of Agreement (MOA) that must be acknowledged and agreed to by the Respondent. Failure to take corrective action or comply with the terms of an MOA shall be cause to bring the original charges for a hearing before the full Board.

Source: Miss. Code Ann. § 73-21-81.

Rule 6.9 Petition for Relief

Any person whose license, registration and/or permit has been denied, suspended, revoked or restricted, whether voluntarily or by action of the Board, shall have the right to petition the Board at reasonable intervals for relief from such action. The Board shall not consider a petition for relief from such action unless an interval of at least one (1) year has passed since the imposition of the penalty or the last Board review. The Board will not entertain a petition for relief if the matter is under appeal.

Source: Miss. Code Ann. § 73-21-103.

Part 3002 Chapter 74: Penalties

Rule 74.1 Uniform Penalty Policy

Any penalty imposed by Board pursuant to a violation of any statute, rule or regulation within the jurisdiction of the Board shall be not less than the minimum nor more than the maximum penalty allowed by Mississippi Code Annotated Sections 73-21-103, 73-21-161, 73-21-191 or any other statute that allows the Board to impose a penalty.

Source: Miss. Code Ann. §§ 73-21-81; 73-21-103; 73-21-163; 73-21-191.

Part 3002 Chapter 8: Duties and Responsibilities of the Executive Director and Associate Director

Rule 8.1 Executive Director Appointed by the Board

The Executive Director (Director) is the executive officer in charge of the office of the Mississippi Board of Pharmacy and he/she shall be appointed by the Board. The Director shall serve as the budget officer and shall make, keep, and be in charge of all records, record books, and any files required to be maintained by the Board. The Director shall attend to the correspondence required by the office and shall perform such other duties as the Board may require in keeping with the office. The Director shall be provided with, supervise, and have the aid of clerical, investigative, and other office staff as necessary for the fulfillment of his/her duties and responsibilities.

Source: Miss. Code Ann. §§ 73-21-79; 73-21-81.

Rule 8.2 General Duties and Responsibilities

The Executive Director shall have, but not be limited to, the following responsibilities:

A. <u>Issuance of all licenses</u>, <u>registrations</u>, and <u>permits to all pharmacists</u>, <u>businesses</u>, <u>facilities</u>, <u>pharmacies</u>, <u>or other persons as authorized by statutes</u>, <u>rules or regulations</u>;

B. Maintaining, preserving, and releasing of any public records which are required to be kept by the Board:

C. Administration of any examinations or tests required under statutes or regulations;

D. Serve as the representative of the Board on any committees, boards or other organizations as necessary to carry out the Board's responsibilities;

E. Act as the Board's agent and cause to be issued and cause to be served, all subpoenas, Orders of the Board, and any Notice of Hearing and Complaint issued to any pharmacist, permit holder, business/facility, registrant, or other person under the jurisdiction of the Board and execute the foregoing for and on behalf of the Board;

F. Provide initiative, leadership, and input into any proposed legislation or regulations pertaining to the practice of pharmacy, the distribution of prescription drugs, pharmacy technicians, and pharmacy externs/interns;

G. Set the agenda for all meetings of the Board, act as recording secretary, and be responsible for the preparation of the Minutes of all meetings of the Board;

H. Serve as the Board's representative in the approval of all continuing education as required by Regulations of the Board;

I. Serve as the Board's representative when interacting and/or cooperating with other state or federal agencies or law enforcement entities;

J. Approve and execute contracts under \$50,000, with the consultation of the Board President;

K. <u>Issue an emergency action or order related to an imminent danger to the public health or safety, with the consultation of the Board President;</u>

L. Any other duty or responsibility as assigned by the Board or Board President.

Source: Miss. Code Ann. §§ 73-21-79; 73-21-81.

Rule 8.2 Associate Director

The Associate Director shall have the duties and responsibilities assigned to him/her by the Executive Director and may perform any/all of the duties and responsibilities of the Executive Director in the absence of the Executive Director or as assigned by the Executive Director.

Source: Miss. Code Ann. § 73-21-81.

Title 30: Professions and Occupations

Part 3002: Mississippi Board of Pharmacy Administrative Rules

Part 3002 Chapter 1: Oral Proceedings On Proposed Regulations

Rule 1.1 Application of Chapter.

This chapter applies to all oral proceedings held for the purpose of providing the public an opportunity to make oral presentations or written input on proposed new rules or regulations, amendments to rules or regulations and proposed repeal of existing rules or regulations before the Board pursuant to the Administrative Procedures Act.

Source: Miss. Code Ann. § 25-43-2.104.

Rule 1.2 When Oral Proceedings will be Scheduled on Proposed Regulations.

The Board will conduct an oral proceeding on a proposed regulation or amendment if requested by a political subdivision, an agency or ten (10) persons in writing within twenty (20) days after the filing of the notice of the proposed regulation.

- A. Each request must be submitted on 8-1/2" x 11" white paper or electronically in a standard letter format, i.e., MS Word, PDF, WordPerfect or other similar format and must be typewritten or printed in legible handwriting.
- B. The request may be in the form of a letter addressed to the Board.
- C. Each request must include the full name, telephone numbers, and mailing address of the requestor(s).
- D. All requests shall be signed by the person filing the request, unless represented by an attorney, in which case the attorney may sign the request.

Source: Miss. Code Ann. §§ 25-43-2.104, 25-43-3.104

Rule 1.3 Notification of Oral Proceeding.

The date, time and place of all oral proceedings shall be filed with the Secretary of State's office and mailed to each requestor. The oral proceedings will be scheduled no earlier than twenty (20) days from the filing of this information with the Secretary of State.

Source: Miss. Code Ann. §§ 25-43-2.104, 25-43-3.104

Rule 1.4 Presiding Officer.

The Board President or his designee, who is familiar with the substance of the proposed regulation, shall preside at the oral proceeding on a proposed regulation.

Source: Miss. Code Ann. § 25-43-2.104

Rule 1.5 Public Presentations and Participation.

A. At an oral proceeding on a proposed regulation, persons may make oral statements and make

documentary and physical submissions, which may include data, views, comments or arguments concerning the proposed regulation.

- B. Persons wishing to make oral presentations at such a proceeding shall notify the Board at least one business day prior to the proceeding and indicate the general subject of their presentations. The presiding officer in his or her discretion may allow individuals to participate that have not previously contacted the Board.
- C. At the proceeding, those who participate shall indicate their names and addresses, identify any persons or organizations they may represent, and provide any other information relating to their participation deemed appropriate by the presiding officer.
- D. The presiding officer may place time limitations on individual oral presentations when necessary to assure the orderly and expeditious conduct of the oral proceeding. To encourage joint oral presentations and to avoid repetition, additional time may be provided for persons whose presentations represent the views of other individuals as well as their own views.
- E. Persons making oral presentations are encouraged to avoid restating matters that have already been submitted in writing.
- F. There shall be no interruption of a participant who has been given the floor by the presiding officer, except that the presiding officer may in his or her discretion interrupt or end the partisan's time where the orderly conduct of the proceeding so requires.

Source: Miss. Code Ann. § 25-43-2.104

Rule 1.6 Conduct of Oral Proceeding.

- A. The presiding officer shall have authority to conduct the proceeding in his or her discretion for the orderly conduct of the proceeding. The presiding officer shall:
 - 1. call proceeding to order;
 - 2. give a brief synopsis of the proposed regulation, a statement of the statutory authority for the proposed regulation, and the reasons provided by the Board for the proposed regulation;
 - call on those individuals who have contacted the Board about speaking on or against the proposed regulation;
 - 4. allow for rebuttal statements following all participant's comments;
 - 5. adjourn the proceeding.
- B. The presiding officer, where time permits and to facilitate the exchange of information, may open the floor to questions or general discussion. The presiding officer may question participants and permit the questioning of participants by other participants about any matter relating to that regulation-making proceeding, including any prior written submissions made by those participants in that proceeding; but no participant shall be required to answer any question.
- C. Physical and Documentary Submissions presented by participants in an oral proceeding shall be submitted to the presiding officer. Such submissions become the property of the Board and are subject to the Board's public records request procedure.
- D. The Board may record oral proceedings by stenographic or electronic means.

Source: Miss. Code Ann. § 25-43-2.104

Part 3002 Chapter 2: Declaratory Opinions

Rule 2.1 Application of Chapter.

This chapter sets forth the Board's rules governing the form, content, and filing of requests for declaratory

opinions, the procedural rights of persons in relation to the written requests, and the Board's procedures regarding the disposition of requests as required by Mississippi Code § 25-43-2.103.

Source: Miss. Code Ann. § 25-43-2.104

Rule 2.2 Scope of Declaratory Opinions.

The Board will issue declaratory opinions regarding the applicability to specified facts of:

- A. a statute administered or enforceable by the Board;
- B. a rule or regulation promulgated by the Board, or
- C. an order issued by the Board.

Source: Miss. Code Ann. § 25-43-2.104.

Rule 2.3 Scope of Declaratory Opinion Request.

A declaratory opinion request must be limited to a single transaction, occurrence or issue.

Source: Miss. Code Ann. § 25-43-2.104.

Rule 2.4 Persons Who May Request Declaratory Opinions.

Any person with a substantial interest in the subject matter may request a declaratory opinion from the Board. "Substantial interest in the subject matter" means: an individual, business, group or other entity that is directly affected by the Board's administration of the laws within its primary jurisdiction. "Primary jurisdiction of the Board" means the Board has a constitutional or statutory grant of authority in the subject matter at issue.

Source: Miss. Code Ann. §§ 25-43-2.103, 25-43-2.104.

Rule 2.5 How to Submit Requests for Declaratory Opinions.

When a person with substantial interest, as required by Section 25-43-2.103 of the Administrative Procedures Act, requests a declaratory opinion, the person must submit a printed, typewritten, or legibly handwritten request.

- A. Each request must be submitted on 8-1/2" x 11" white paper or electronically in a standard letter format, i.e., MS Word, PDF, WordPerfect or other similar format.
- B. The request may be in the form of a letter addressed to the Board or in the form of a pleading as if filed with a court.
- C. Each request must include the full name, telephone numbers, and mailing address of the requestor(s).
- D. All requests shall be signed by the person filing the request, unless represented by an attorney, in which case the attorney may sign the request.
- E. Each request must clearly state that it is a request for a declaratory opinion.
- F. All requests must be mailed, emailed, delivered or transmitted via facsimile to the Board. No oral or telephone requests will be accepted for official declaratory opinions.

Source: Miss. Code Ann. § 25-43-2.104.

Rule 2.6 Signature Attestation.

Any party who signs the request shall attest that the request complies with the requirements set forth in these rules, including but not limited to a full, complete, and accurate statement of relevant facts and that

there are no related proceedings pending before any agency, administrative, or judicial tribunal.

Source: Miss. Code Ann. § 25-43-2.104.

Rule 2.7 Content of Request.

Each request must contain the following:

- A. A clear identification of the statute, rule, or order at issue;
- B. The question for the declaratory opinion;
- C. A clear and concise statement of all facts relevant to the question presented;
- D. The identity of all other known persons involved in or impacted by the facts giving rise to the request including their relationship to the facts, and their name, mailing address, and telephone number:
- E. A statement sufficient to show that the requestor has a substantial interest in the subject matter of the request;
- F. A suggested proposed opinion, stating the answers desired by requestor and a summary of the reasons in support of those answers;

Source: Miss. Code Ann. §§ 25-43-2.103, 25-43-2.104.

Rule 2.8 Reasons for Refusal to Issue a Declaratory Opinion Upon a Request.

The Board may, for good cause, refuse to issue a declaratory opinion. The circumstances in which declaratory opinions will not be issued include, but are not necessarily limited to:

- A. The matter is outside the primary jurisdiction of the Board;
- B. Lack of clarity concerning the question presented;
- C. There is pending or anticipated litigation, administrative action, or other adjudication which may either answer the question presented by the request or otherwise make an answer unnecessary;
- D. The statute, rule, or order on which a declaratory opinion is sought is clear and not in need of interpretation to answer the question presented by the request;
- E. The facts presented in the request are not sufficient to answer the question presented;
- F. The request fails to contain information required by these rules or the requestor failed to follow the procedure set forth in these rules;
- G. The request seeks to resolve issues which have become moot or are abstract or hypothetical such that the requestor is not substantially affected by the rule, statute, or order on which a declaratory opinion is sought;
- H. No controversy exists or is certain to arise which raises a question concerning the application of the statute, rule, or order;
- The question presented by the request concerns the legal validity of a statute, rule, or order;
- J. The request is not based upon facts calculated to aid in the planning of future conduct, but is, instead, based on past conduct in an effort to establish the effect of that conduct;
- K. No clear answer is determinable;
- L. The question presented by the request involves the application of a criminal statute or sets forth facts which may constitute a crime;
- M. The answer to the question presented would require the disclosure of information which is privileged or otherwise protected by law from disclosure;
- N. The question is currently the subject of an Attorney General's opinion request or has been answered by an Attorney General's opinion;
- O. A similar request is pending before this agency, or any other agency, or a proceeding is pending on the same subject matter before any agency, administrative or judicial tribunal, or where such

an opinion would constitute the unauthorized practice of law; or

P. The question involves eligibility for a license, permit, certificate or other approval by the Board or some other agency and there is a statutory or regulatory application process by which eligibility for said license, permit, or certificate or other approval may be determined.

Source: Miss. Code Ann. §§ 25-43-2.103, 25-43-2.104.

Rule 2.9 Agency Response.

Within forty-five (45) days after the receipt of a request for a declaratory opinion which complies with the requirements of these rules, the Board shall, in writing:

- A. Issue an opinion declaring the applicability of the statute, rule, or order to the specified circumstances;
- B. Agree to issue a declaratory opinion by a specified time but no later than ninety (90) days after receipt of the written request; or
- C. Decline to issue a declaratory opinion, stating the reasons for its action.

The forty-five (45) day period shall begin on the first business day after which the request is received by the Board.

Source: Miss. Code Ann. §§ 25-43-2.103, 25-43-2.104.

Rule 2.10 Availability of Declaratory Opinions and Requests for Opinions.

Declaratory opinions and requests for declaratory opinions shall be available for public inspection and copying in accordance with the Public Records Act and the Board's public records request procedure. All declaratory opinions and requests shall be indexed by requestor's name, subject and date of issuance. Declaratory opinions and requests which contain information which is confidential or exempt from disclosure under the Mississippi Public Records Act or other laws shall be exempt from this requirement and shall remain confidential.

Source: Miss. Code Ann. §§ 25-43-2.103, 25-43-2.104.

Rule 2.11 Notice by Board to third parties.

The Board may give notice to any person, agency or entity that a declaratory opinion has been requested and may receive and consider data, facts, arguments and opinions from other persons, agencies or other entities other than the requestor.

Source: Miss. Code Ann. § 25-43-2.104.

Rule 2.12 Effect of a Declaratory Opinion.

The Board will not pursue any civil, criminal or administrative action against a person who is issued a declaratory opinion from the Board and who, in good faith, follows the direction of the opinion and acts in accordance therewith unless a court of competent jurisdiction holds that the opinion is manifestly wrong. Any declaratory opinion rendered by the Board shall be binding only on the Board and the person to whom the opinion is issued. No declaratory opinion will be used as precedent for any other transaction or occurrence beyond that set forth by the requesting person.

Source: Miss. Code Ann. §§ 25-43-2.103, 25-43-2.104.

Part 3002 Chapter 3: Public Records

Rule 3.1 Public Record Requests Procedures.

This rule establishes procedures and fees associated with all public requests for copies and/or inspection of public documents.

A. Submission of Requests.

- 1. All requests for information should be submitted to the Mississippi Board of Pharmacy either in writing or via email.
- 2. No verbal or telephone requests can be accepted.
- 3. The request should specifically outline the records that are being requested.

B. Timetable for processing.

All document requests will be approved or denied within seven (7) business days after the request is received. In the event of a denial for all or part of the request, the Board will provide an explanation of the denial to the requestor in writing. If the requested information is unable to be produced by the seventh day after the request is made, the Board will provide a written explanation regarding why the document cannot be produced during that timeframe. Unless there is a mutual agreement of the parties, in no case shall the production of the requested records, after timely payment and unless otherwise exempt, be any later than fourteen (14) working days from the receipt of the request.

C. Exempt Documents.

Some documents are exempt from publication such as personnel records, attorney communications and work products of attorneys.

D. Third Party Information.

Records furnished to the Board by third parties which contain trade secrets or confidential commercial or financial information shall not be subject to inspection, examination, copying or reproduction until the third party has been advised that the documents will be released. Further, no third-party information will be released if a third party obtains a court order prohibiting the same. The requestor will be notified of any court orders that prohibit the release of the requested information.

E. Assessment of costs to the Requestor.

Payment for information requested must be made in advance of receipt of documents and must be sufficient to cover the actual costs for the Board to furnish the information. Such costs include, but are not limited to, staff time: to evaluate the request, to retrieve any relevant files, to organize the information, to notify any Third Parties, to develop a cost estimate and schedule, to reproduce the material, and to the deliver the information requested.

1. No cash, credit or debit cards, or personal checks can be accepted. Money orders, certified

checks, or corporate checks are accepted.

- 2. An estimated cost will be provided to the requestor based on the volume of information, the format in which the information is stored and requested, and whether or not third-party information has been requested. The requestor may submit payment for processing of the request, amend the request or withdraw the request. The requestor should submit written notice of his/her intent to either proceed or withdraw the request.
- 3. If no response is given by the requestor within thirty (30) days of the estimated cost notification being sent, the Board will proceed no further with the request. If at a later date, the requestor decides to proceed with the request, he/she should submit a new request.
- 4. Timely payment under paragraph B. means payment received by the next business day after the estimated cost notification is provided to the requestor. By delaying the payment of the estimated fee past the next business day, the requestor acknowledges there may be a delay in

the delivery of the requested documents. No request will be processed until payment is received.

5. The decision to charge for public records is at the discretion of the Board.

F. Requests for Document Inspections.

The requestor will be billed for the total amount of time expended by employees of the Board assisting with the inspection of documents. Additional fees incident to document production may be assessed.

G. Public Information via the Internet.
Some information pertaining to the Mississippi Board of Pharmacy is available free of charge on the internet at www.mbp.state.ms.us.

Source: Miss. Code Ann. §§ 25-61-1 et seq., 73-21-81

Rule 3.2 Licensure Applications Exempt from Public Access.

All applications for licensure in the possession of the Board are exempt from the provisions of the Mississippi Public Records Act of 1983 pursuant to Mississippi Code Annotated Section 73-52-1.

Source: Miss. Code Ann. § 73-52-1.

Part 3002 Chapter 4: Background Checks

Rule 4.1 Background Check Procedures.

The Board shall conduct background checks on any individual who applies for a license, registration or permit as required by law. Background checks shall include, but not be limited to, a criminal history records check requiring the applicant to be fingerprinted.

Source: Miss. Code Ann. §§ 73-21-81, 73-21-85, 73-21-111, 73-21-126.

Rule 4.2 Petition for Determination.

An individual may petition the Board for a determination of whether the individual's criminal record will disqualify the individual from obtaining a license, registration or permit. The determination petition shall be filed on a form supplied by the Board and accompanied by a fee of Twenty-Five Dollars (\$25.00).

Source: Miss. Code Ann. § 73-77-9.

Rule 4.3 Determination Factors.

The following factors shall be used to determine if an applicant with a disqualifying criminal conviction will be denied a license:

- A. The nature and seriousness of the crime for which the individual was convicted;
- B. The passage of time since the commission of the crime;
- C. The relationship of the crime to the ability, capacity, and fitness required to perform the duties and discharge the responsibilities of the occupation; and
- D. Any evidence of rehabilitation or treatment undertaken by the individual that might mitigate against a direct relation.

Source: Miss. Code Ann. § 73-77-7.

If the Board denies an individual a license, registration or permit solely or in part because of the individual's prior conviction of a crime, the Board shall notify the individual in writing of the following:

- A. The grounds and reasons for the denial or disqualification;
- B. That the individual has the right to a hearing to challenge the Board's decision;
- C. The earliest date the person may reapply for a license, registration or permit; and
- D. That the evidence of rehabilitation may be considered upon reapplication.

Source: Miss. Code Ann. § 73-77-9.

Rule 4.5 Disqualifying Crimes

An individual may be denied a license, registration or permit based on a conviction, guilty plea and/or a plea of nolo contender to a felony, which includes, but is not limited to, any of the following:

- A. Any controlled substance violation;
- B. Embezzlement
- C. Shoplifting
- D. Theft
- E. Forgery
- F. Burglary
- G. Identity theft

In addition, the accumulation of multiple convictions, including misdemeanor convictions, and pending unresolved charges may be used to determine if an individual shall be denied a license, registration or permit.

Source: Miss. Code Ann. § 73-21-81.

Rule 4.6 Mitigating Factors

Notwithstanding Rule 4.5, any criminal conviction beyond ten (10) years prior to the application shall not disqualify an individual unless extenuating circumstances exist. Those extenuating circumstances shall be enumerated in the disqualifying determination notification. Other mitigating factors to be considered in determining whether the individual's criminal record will disqualify the individual from obtaining a license, registration or permit may include, but need not be limited to:

- A. age at which the crime was committed;
- B. circumstances surrounding the crime;
- C. length of time since the conviction and criminal history since the conviction;
- D. work history;
- E. current employment and character references; and
- F. other evidence demonstrating the ability of the person to perform the employment responsibilities competently and that the person does not pose a threat to the health or safety of the public.

Source: Miss. Code Ann. § 73-21-81.

Part 3002 Chapter 5: Disciplinary Actions

Rule 5.1 Grounds for Disciplinary Actions.

A. The Board may refuse to issue or renew, or may suspend, reprimand, revoke or restrict the license, registration or permit of any person upon one or more of the provisions listed in Mississippi Code Annotated Section 73-21-97.

- B. Unprofessional conduct. Unprofessional conduct shall include, but not be limited to:
 - 1. The publication or circulation of false, misleading, or otherwise deceptive statements concerning the practice of pharmacy;
 - 2. Attempting to circumvent the patient counseling requirements, or discouraging the patient from receiving patient counseling concerning their prescription drug orders;
 - 3. The illegal use or disclosure of Protected Health Information (PHI) or other confidential patient information; failure to maintain adequate records, systems, and security to protect against the illegal use or disclosure of PHI or other confidential patient information; or failure to maintain adequate records to account for disclosures of PHI;
 - 4. Dispensing, selling, bartering, receiving or maintaining drugs or devices which is known or should have been known to have been stolen or diverted from the purpose for which they were distributed by a legitimate source;
 - 5. Engaging in conduct likely to deceive, defraud, or harm the public, or demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from the standards of care ordinarily exercised by a pharmacist, with proof of actual injury not having to be established;
 - 6. Selling a drug for which a prescription drug order from a practitioner is required, without having received a valid prescription drug order for the drug;
 - Failing to maintain complete and accurate records of all drugs received, dispensed, or disposed of in compliance with the Federal laws and regulations and State laws, rules and regulations;
 - 8. Failure to report fraudulent prescription activity to the Board or other appropriate authorities;
 - 9. Obtaining any remuneration by fraud, misrepresentation, or deception, including, but not limited to, receiving remuneration for amending or modifying, or attempting to amend or modify, a patient's pharmacist care services, absent a clear benefit to the patient.
 - 10. Filing a claim or assisting in the filing of a claim for reimbursement for drugs or professional services which were not provided, or which were not authorized to be provided.
- C. Physical or mental incapacity of a nature that prevents a pharmacist, a pharmacy intern/extern, or a pharmacy technician from engaging in the practice of pharmacy or assisting in the practice of pharmacy with reasonable skill, confidence and safety to the public;
- D. Being found guilty by a court of competent jurisdiction of one or more of the following:
 - 1. A felony;
 - 2 Any act involving moral turpitude or gross immorality; or
 - 3. Violation of pharmacy or drug laws of this state or rules and regulations pertaining thereto, or of statutes, rules or regulations of any other state or the federal government;
- E. Fraud or intentional misrepresentation by a licensee, registrant or permit holder in securing the issuance or renewal of a license, registration or permit;
- F. Violation of pharmacy or drug laws of any other state or the federal government or the rules/regulations pertaining thereto;
- G. Violation of any of the provisions of the Mississippi Uniform Controlled Substances Law;
- H. Failure to immediately report directly to the Board, losses or suspected losses of controlled substances or prescription drugs;
- Theft or embezzlement of prescription drugs, controlled substances, medical devices, funds or anything of value from a permitted facility;
- J. Termination of employees suspected of theft of pharmaceuticals, or merchandise or anything of value without contacting the Board prior to termination;
- K. Failure of a pharmacist licensed by the Mississippi Board of Pharmacy to register as a user of the Prescription Monitoring Program (PMP);

- L. The unlawful disclosure of information from the PMP or using information obtained from the PMP for unlawful or unethical purposes;
- M. Receiving, dispensing, selling, bartering or maintaining a prescription drug sample unless the pharmacy is owned by a charitable organization and is not operated for profit and has prior approval in writing by the Board. Institutional pharmacies may receive, dispense and maintain prescription drug samples that are provided by a practitioner and intended solely for administration to his/her patients confined to the institution provided no charge is made to the patient by the institution for the sample;
- N. No pharmacist shall have possession of a prescription drug sample unless such sample is for treatment of a diagnosed personal medical condition;
- O. Jeopardizing, compromising, interfering or failing to cooperate with any lawful investigation conducted by the Board or any state or federal regulatory or law enforcement agency;
- P. Failure to furnish the Board, its agents or representatives any information legally requested by the Board, or retaliation against pharmacy employees for providing information to the Board;
- Q. Destruction, removal or tampering with any prescription drug, controlled substance, or medical device placed under seal, embargoed, or quarantined by the Board or any representative of the Board;
- R. Any act by any person which subverts the authority of the pharmacist-in-charge by impeding the management of the prescription department or the practice of pharmacy in the compliance with federal and state drug or pharmacy laws and regulations;
- S. Failure to produce evidence of continuing educations credits as required by regulation.

Source: Miss. Code Ann. §§ 73-21-81, 73-21-97

Part 3002 Chapter 6: Disciplinary Proceedings

Rule 6.1 Disciplinary Resolutions.

All disciplinary proceedings initiated by the Board shall be brought to a final resolution through one of the following means:

- A. Formal Disciplinary hearing before the Board;
- B. Acceptance by the Board of a mutually agreeable Settlement Order in lieu of a hearing;
- C. Issuance of an Administrative Citation by the Investigations Review Committee (IRC) and payment of a fine by the Respondent in lieu of a hearing; or
- D. Dismissal of the case.

Source: Miss. Code Ann. § 73-21-81.

Rule 6.2 Issuance of Subpoenas.

The Board, acting by and through its executive director, is authorized and empowered to issue subpoenas for the attendance of witnesses and the production of books and papers at a hearing. Process issued by the Board shall extend to all parts of the state and shall be served by any person designated by the Board for such service. Where any witness fails or refuses to attend upon a subpoena issued by the Board, refuses to testify, or refuses to produce any books and papers the production of which is called for by a subpoena, the attendance of such witness, the giving of his testimony or the production of the books and papers shall be enforced by any court of competent jurisdiction of this state in the manner provided for the enforcement of attendance and testimony of witnesses in civil cases in the courts of this state.

A. All requests for subpoenas shall be submitted at least fifteen (15) days prior to the scheduled

hearing.

- B. The request must contain the identity and address of the individual to be subpoenaed.
- C. If the subpoena is for records or documents, the request must include the identity and address of the custodian of such records, along with a concise description of the records to be subpoenaed.
- D. The Board will serve all subpoenas by registered mail, return receipt requested or by hand delivery.
- E. The Board shall charge a reasonable fee for each subpoena, not to exceed thirty-five dollars (\$35.00), for preparation and service of each subpoena.

Source: Miss. Code Ann. §§ 73-21-99, 73-21-81.

Rule 6.3 Prehearing Motions.

All prehearing motions must be filed with the Board at least fifteen (15) days prior to the scheduled hearing. The Board President shall have the authority to rule on motions that are filed pursuant to this Rule. The Respondent and the Board counsel will be notified of the ruling on the motion promptly. The ruling of the Board President will be entered into the record at the scheduled hearing date. Motions for continuances shall be handled pursuant to Rule 6.4.

Source: Miss. Code Ann. § 73-21-81.

Rule 6.4 Hearing Continuances.

A motion for continuance must be filed with the Board at least fifteen (15) days prior to the scheduled hearing, or upon a showing of good cause, at any time prior to the hearing. A scheduling conflict on behalf of the Respondent or Respondent's counsel shall be considered good cause, and will be liberally granted, if written proof of the scheduling conflict is submitted to the Board at least fifteen (15) days prior to the scheduled hearing. A second continuance based on scheduling conflicts shall not be granted by the Board. Failure to retain counsel in a timely manner on the part of the Respondent shall not be considered good cause. The Board President or Executive Director shall have the authority to rule on motions for continuance that are filed pursuant to this Rule. The Respondent and the Board counsel will be notified of the ruling on the motion promptly. The ruling of the Board President or Executive Director will be entered into the record at the scheduled hearing date and the rescheduled hearing date will be set if the motion for continuance is granted.

Source: Miss. Code Ann. § 73-21-81.

Rule 6.5 Hearing Procedures.

- A. All hearings shall be conducted by the Board, which shall not be bound by strict rules of procedure or by the laws of evidence in the conduct of its proceedings.
- B. The hearing shall be held at the time and place as specified in the Notice of Hearing and Complaint unless continued for good cause.
- C. All hearings are open to the public, subject to the Board entering executive session, which shall be closed to the public.
- D. The Board President, Vice-President or senior member of the Board will preside over the hearing.
- E. The Board may be assisted by a hearing officer who shall advise the Board on matters of law and procedure and rule on all objections and motions. The hearing officer's rulings on matters

of law and procedure are advisory.

- F. Any Board members that participated in the IRC for the matter before the Board will recuse themselves and not participate in the hearing.
- G. All hearings shall be recorded and the Board, or court reporter, shall administer oaths as may be necessary for the proper conduct of the hearing.
- H. The Respondent may retain legal counsel or may represent themselves.
- I. Upon direction from the Presiding Officer, the Board counsel shall present evidence and call witnesses to support the charges filed in the Notice of Hearing and Complaint.
- J. The Respondent or Respondent's counsel may present evidence or call witnesses to answer the charges filed in the Notice of Hearing and Complaint.
- K. The Board shall not hear evidence nor make findings on any violations that were not part of the Notice of Hearing and Complaint.
- L. All witnesses at the hearing shall be subject to direct examination, cross examination and questions by the Board. Re-direct and re-cross examinations shall be at the discretion of the Board.
- M. The Board should adjudicate each charge and make findings of fact on each charge as presented in the Notice of Hearing and Complaint. Any determination by the Board shall be based upon sufficient evidence to sustain it.
- N. The Board shall, within thirty (30) days after the conclusion of the hearing, reduce its decision to writing and forward an attested true copy to the last-known residence or business address of the licensee or permit holder by way of United States first-class, certified mail, postage prepaid.

Source: Miss. Code Ann. §§ 73-21-99; 73-21-81.

Rule 6.6 Settlement Negotiations and Agreed Settlement Orders.

When the Respondent has been duly served with a Notice of Hearing and Complaint, the Respondent and/or Respondent's counsel may request Settlement negotiations for the purpose of possible resolution of the matter or for purpose of simplifying the issues for hearing or promoting stipulations as to facts and proposed evidentiary offerings which will not be disputed at hearing.

- A. The Respondent and/or his counsel and Board Counsel shall participate in the settlement negotiations. Board members who served on the Investigations Review Committee (IRC) for the matter and compliance agents who investigated the matter shall be consulted during the settlement negotiations. Other Board members may not participate nor have knowledge or input into any of the settlement negotiations.
- B. Informal Discovery or exchange of information may be accomplished during the settlement negotiations.
- C. Any action which the Board may take following a full disciplinary hearing may be taken by Agreed Settlement Order.
- D. Any proposed Agreed Settlement Order must be approved by both Board members who served on the Investigations Review Committee (IRC) for the matter. The proposed Agreed Settlement Order shall be presented to the Board at the scheduled Hearing date and time. The terms of the Agreed Settlement Order are not effective until approved by the Board.
- E. The Respondent has the obligation to personally appear before the Board on the scheduled hearing date to answer any questions which the Board may have prior to approving the proposed Agreed Settlement Order.
- F. Failure of the Board to approve the proposed Agreed Settlement Order shall result in a formal disciplinary hearing before the Board on a rescheduled hearing date.

Source: Miss. Code Ann. § 73-21-81.

Rule 6.7 Administrative Citations.

The IRC may include an Administrative Citation with the Notice of Hearing and Complaint. In lieu of a formal disciplinary hearing, the Respondent has the option to settle the matter through the payment of a fine and compliance with imposed conditions. If the Respondent does not accept the fine and conditions or respond to the Administrative Citation instructions within the time specified in the Notice, the matter shall proceed to a formal disciplinary hearing before the Board.

Source: Miss. Code Ann. § 73-21-81.

Rule 6.8 Additional Conditions for Administrative Citations.

In addition to any fine imposed, an Administrative Citation may include corrective action or additional conditions imposed by the IRC through a Memorandum of Agreement (MOA) that must be acknowledged and agreed to by the Respondent. Failure to take corrective action or comply with the terms of an MOA shall be cause to bring the original charges for a hearing before the full Board.

Source: Miss. Code Ann. § 73-21-81.

Rule 6.9 Petition for Relief

Any person whose license, registration and/or permit has been denied, suspended, revoked or restricted, whether voluntarily or by action of the Board, shall have the right to petition the Board at reasonable intervals for relief from such action. The Board shall not consider a petition for relief from such action unless an interval of at least one (1) year has passed since the imposition of the penalty or the last Board review. The Board will not entertain a petition for relief if the matter is under appeal.

Source: Miss. Code Ann. § 73-21-103.

Part 3002 Chapter 7: Penalties

Rule 7.1 Uniform Penalty Policy

Any penalty imposed by Board pursuant to a violation of any statute, rule or regulation within the jurisdiction of the Board shall be not less than the minimum nor more than the maximum penalty allowed by Mississippi Code Annotated Sections 73-21-103, 73-21-161, 73-21-191 or any other statute that allows the Board to impose a penalty.

Source: Miss. Code Ann. §§ 73-21-81; 73-21-103; 73-21-163; 73-21-191.

Part 3002 Chapter 8: Duties and Responsibilities of the Executive Director and Associate Director

Rule 8.1 Executive Director Appointed by the Board

The Executive Director (Director) is the executive officer in charge of the office of the Mississippi Board of Pharmacy and he/she shall be appointed by the Board. The Director shall serve as the budget officer and shall make, keep, and be in charge of all records, record books, and any files required to be maintained by the Board. The Director shall attend to the correspondence required by the office and shall perform such other duties as the Board may require in keeping with the office. The Director shall be provided with, supervise, and have the aid of clerical, investigative, and other office staff as necessary for the fulfillment of his/her

duties and responsibilities.

Source: Miss. Code Ann. §§ 73-21-79; 73-21-81.

Rule 8.2 General Duties and Responsibilities

The Executive Director shall have, but not be limited to, the following responsibilities:

- A. Issuance of all licenses, registrations, and permits to all pharmacists, businesses, facilities, pharmacies, or other persons as authorized by statutes, rules or regulations;
- B. Maintaining, preserving, and releasing of any public records which are required to be kept by the Board;
- C. Administration of any examinations or tests required under statutes or regulations;
- D. Serve as the representative of the Board on any committees, boards or other organizations as necessary to carry out the Board's responsibilities;
- E. Act as the Board's agent and cause to be issued and cause to be served, all subpoenas, Orders of the Board, and any Notice of Hearing and Complaint issued to any pharmacist, permit holder, business/facility, registrant, or other person under the jurisdiction of the Board and execute the foregoing for and on behalf of the Board;
- F. Provide initiative, leadership, and input into any proposed legislation or regulations pertaining to the practice of pharmacy, the distribution of prescription drugs, pharmacy technicians, and pharmacy externs/interns;
- G. Set the agenda for all meetings of the Board, act as recording secretary, and be responsible for the preparation of the Minutes of all meetings of the Board;
- H. Serve as the Board's representative in the approval of all continuing education as required by Regulations of the Board;
- I. Serve as the Board's representative when interacting and/or cooperating with other state or federal agencies or law enforcement entities;
- J. Any other duty or responsibility as assigned by the Board or Board President.

Source: Miss. Code Ann. §§ 73-21-79; 73-21-81.

Rule 8.2 Associate Director

The Associate Director shall have the duties and responsibilities assigned to him/her by the Executive Director and may perform any/all of the duties and responsibilities of the Executive Director in the absence of the Executive Director or as assigned by the Executive Director.

Source: Miss. Code Ann. § 73-21-81.

ARTICLE XXX: LONG-TERM CARE FACILITIES (LTCF)

A. CONSULTING PHARMACISTS TO NURSING HOMES

- Unless specifically authorized by the Board, no person shall serve as a consultant pharmacist or act or purport to act in this capacity to any nursing home unless he/she possesses the following qualifications:
 - A. Have and maintain a license to practice pharmacy within the State of Mississippi;
 - B. Have attended within the last two years a training course of not less than eight (8) hours in LTC or geriatric related pharmacy services that has been approved by the Board of Pharmacy;
 - C. In order to be approved by the Board of Pharmacy, the training course for a consultant pharmacist shall provide instruction in the areas of clinical pharmacy services, drug distribution systems and state and federal pharmacy regulations governing the practice of long-term care pharmacy.
- For purposes of this ARTICLE, a Consultant Pharmacist shall mean a Mississippi licensed pharmacist who is responsible for developing, coordinating and supervising pharmaceutical services on a regularly scheduled basis in long term care facility, as well as the following responsibilities.
 - A. Reviewing policies and procedures regarding the distribution and storage of medications within the facility and as necessary making recommendations to the facility and provider pharmacist;
 - B. Monitoring utilization and therapeutic response of medications prescribed for and administered to residents of the facility as well as providing consultation on matters related to medications;
 - C. Serving as a resource for pharmacy related educational services within the facility;
 - Communication and discussion with the provider pharmacist regarding areas of concern and resolution thereof;
 - E. Serving on appropriate committees;
 - F. Supervising and assisting in the disposal of all discontinued, expired, or otherwise unneeded controlled substance medications;
 - G. Reviewing records of the destruction of all medications and verification of the reasons for destruction;
 - H. Ensuring that complete and accurate records of the acquisition and disposition of controlled substance medications which have been dispensed for residents of the institutional facility are maintained;
 - I. Attending, within the last two (2) years, a consultant pharmacist seminar which has been approved by the Board;
 - J. Maintain consultant pharmacist eligibility as described in Section 1.
- 3. A Long-Term Care Facility which is permitted by the Board and where the services of a consultant pharmacist are required shall have the following responsibilities:
 - A. Policy Manual. The institution shall develop policies and procedures regarding

pharmacy services which include, but are not limited to, proper labeling of patient medications and emergency drugs, security of patient medications and emergency drugs, administration and controlled substances record-keeping and accountability. This procedural manual shall be the responsibility of the institution and is to be promulgated with the concurrence of the consultant pharmacist, nursing home administrator and the directors of medical and nursing services.

B. Reference. Reference materials shall be readily available in the nursing stations(s) and contain current editions of appropriate reference materials as may be deemed necessary

by the consultant pharmacist and the medical and nursing directors.

C. Reporting. The institution shall establish policies and procedures which assures that all medication errors and adverse drug reactions are reported immediately to the patient's physician and the consultant pharmacist and an entry made in the patient's record. These procedures should assure that corrective measures are implemented. The consultant pharmacist should be notified within twenty-four (24) hours of discovery of any discrepancy in counts or of a loss of any controlled substances. The consultant pharmacist should notify the Board immediately upon his/her notification with a plan to investigate the loss.

D. Emergency Medication Kits. The institution shall establish policies and procedures which assure that the institution is in compliance with ARTICLE XXXV INSTITUTIONAL EMERGENCY MEDICATION KIT PERMITS (FIRST DOSE KITS) FOR LONG TERM CARE FACILITIES AND OTHER APPROVED INSTITUTIONAL FACILITIES of these Pharmacy Practice Regulations.

- E. Disposal of Patient Medication. The Long-Term Care Facility, with the assistance of the consultant pharmacist shall establish policies and procedures which assures the proper disposal of any discontinued, expired, or otherwise unwanted patient medications. Policies and procedures should ensure that any medication removed subject to destruction, does not have a current valid order for the medication on the patient's medication profile. Policies and Procedures for disposal of these medications should include as follows:
 - (1) All unwanted patient medications should remain in a secured location at the institution until proper disposal is made;
 - (2) Documentation of any disposal of patient medications should include a paper trail from the time the medication was logged into the discontinued drug storage area until destruction is made. This paper trail shall include a log containing the patient name, medication and strength, and quantity to be destroyed as well as the initials of the person logging in the medication for destruction. This documentation should be stored at the institution and be readily retrievable for inspection by Board Agents for a period of two (2) years;
 - (3) Discontinued and unwanted patient medications shall be destroyed on a timely basis not to exceed sixty (60) days from the date that the medication was discontinued. Any such destruction shall be performed by two licensed personnel and documented by their signatures. The consultant pharmacist is valid personnel to participate in this activity.
- 4. A consultant pharmacist shall document communication of the findings of his/her reviews to the attending physician and director of nursing along with their responses and maintain these records for a period of two (2) years. A copy of these reviews must be maintained at the facility and available for inspection.

B. UNIT DOSE DISPENSING FOR LTCF

Definitions:

For the purpose of this ARTICLE XXX, the following definitions apply:

- (1) "Provider pharmacist, means a pharmacist licensed to practice pharmacy by the Board who is responsible for supervising the accurate dispensing and proper delivery of medications to a (LTCF) located within this state. These services shall include, at a minimum, proper medication labeling, storage, transport, record keeping, and prospective drug utilization review in compliance with all federal, state and local laws and regulations.
- (2) "Provider Pharmacy" means any pharmacy permitted by the Board where medications are dispensed to residents of a long-term care facility located in this state.
- (3) "Unit dose package" is a package, which contains one dose of a medication for administration to a patient. A unit dose package may contain one or more individual units or fractions of units of a distinct medication.
- (4) "Unit of issue package" is a medication package issued by a provider pharmacy, which provides multiple units/dosages of medications attached to each other but separated in a card or a specifically designed container.
- (5) "Multi-dose strip packaging" (MDS) is a medication package issued by a provider pharmacy which provides multiple distinct medications to be administered at the same time.
- 1. Packaging for all non-sterile medications stored and dispensed in single unit dose, unit dose, unit of issue or MDS packages for use in a LTCF shall:
 - A. Preserve and protect the identity and integrity of the drug medication from the point of packaging to the point of patient administration;
 - B. When packaged by the manufacturer or distributor, be in compliance with Federal Food and Drug Administration guidelines;
 - C. Shall be in containers clean and free of extraneous matter when the dosage unit(s) are placed into the package;
 - D. Utilize containers, which are classified according to USP Standard 671 as being Class A or Class B for oral solid dosage forms or tight containers for liquid dosage forms.
- 2. Labeling for unit dose packaging or multi-dose strip packaging shall comply with the following;
 - A. When packaged by the manufacturer or distributor shall be

- properly labeled according to Federal Food and Drug Administration requirements;
- B. Unit doses or multi-dose strip packaging packaged by the provider pharmacy shall be properly labeled according to ARTICLE XXIX. If needed, the provider pharmacy may utilize an external container to provide required labeling elements. The name of the patient, drug, dosage strength and form must be on the primary packaging.
- C. Labeling for unit of issue packages shall contain the following information: Name and facility specific patient identifier (e.g. room or bed number of patient), name of prescribing practitioner, name and strength of drug, directions for use, and the name and address of the provider pharmacy when utilized for patients in an (LTCF) setting.
- If a pharmacist selects a generically equivalent drug product for a brand name drug
 product prescribed by a practitioner, labeling must comply with ARTICLE X of the
 Pharmacy Practice Regulations of the Board.
- 4. Expiration dating for non-sterile medications dispensed and packaged into single unit doses, unit doses, and unit of issue packages shall meet the following conditions:
 - A. Not exceed the manufacturer's original expiration date;
 - B. Have an expiration date assigned based on the unit dose container manufacturer's recommendations;
 - C. May exceed ninety (90) days from date of repackaging provided that the container is classified according to USP Standard 671 as being Class A or Class B for oral solid dose forms or is a tight container for liquid dosage forms, the container is light resistant when the manufacturer has labeled the drug product "sensitive to light", and the expiration date is not greater than twelve (12) months;
 - D. Drugs or dosage forms having known stability problems or that are not packaged as defined in Article XXX are assigned an expiration date of less than ninety (90) days.

The shortest time span of any of the listed conditions shall be the expiration date assigned to the medication.

C. RETURN OF MEDICATIONS FROM AN LTCF INSTITUTIONAL FACILITY TO THE PROVIDER PHARMACY

- Medication that has been dispensed for a patient residing in an LTCF facility may be returned to the provider pharmacy provided that the medication has an approved reason for return as follows:
 - A. Medication was discontinued prior to delivery;
 - B. Patient no longer a patient or expired prior to medication being delivered;
 - C. Medication dosage changed prior to delivery;
 - D. Medication is considered to be dispensed when it leaves the dispensing pharmacy and is delivered to the LTCF.

Any medication subject to return must be intact with no doses removed from blister package (unit dose) and must not have had contact with other medications. Medications, which have been dispensed and placed in bulk packages and accepted by a responsible person at the LTCF, shall not be returned to the dispensing pharmacy for any reason. All medication subject to return, must be returned to the provider pharmacy by pharmacy personnel within five (5) days. No controlled substances may be returned.

The provider pharmacy must implement approved procedures, which ensure that any returned medication has been properly stored, has not been tampered with, and the integrity of the medication remains intact. Paper trails tracking these procedures must be maintained by the provider pharmacy for a period of two (2) years and be readily retrievable for inspection by agents of the Board.

ARTICLE XXX INSTITUTIONAL/LONG-TERM CARE FACILITIES (LTCF)

A. CONSULTING PHARMACISTS TO INSTITUTIONAL (LTC) FACILITIES NURSING HOMES

- 1. Unless specifically authorized by the Board to do so, no person shall serve as a consultant pharmacist or act or purport to act in this capacity to any <u>nursing home</u> institutional facility unless he/she possesses the following qualifications:
 - A. Have and maintain a license to practice pharmacy within the State of Mississippi;
 - B. Have attended within the last two years a training course of not less than eight (8) hours in <u>LTC or geriatric related</u> institutional pharmacy services that has been approved by the Board of Pharmacy;
 - C. In order to be approved by the Board of Pharmacy, the training course for a consultant pharmacist to an institutional facility shall provide instruction in the areas of clinical pharmacy services, drug distribution systems and state and federal pharmacy regulations governing the practice of institutional long term care pharmacy.
- For purposes of this ARTICLE, a Consultant Pharmacist shall mean a Mississippi licensed pharmacist who is responsible for developing, coordinating and supervising pharmaceutical services on a regularly scheduled basis in an institutional facility long term care facility, as well as the following responsibilities.
 - Reviewing policies and procedures regarding the distribution and storage of medications within the facility and as necessary making recommendations to the facility and provider pharmacist;
 - B. Monitoring utilization and therapeutic response of medications prescribed for and administered to residents of the facility as well as providing consultation on matters related to medications;
 - C. Serving as a resource for pharmacy related educational services within the facility;
 - D. Communication and discussion with the provider pharmacist regarding areas of concern and resolution thereof;

- E. Serving on appropriate committees;
- F. Supervising and assisting in the disposal of all discontinued, expired, or otherwise un-needed controlled substance medications;
- G. Reviewing records of the destruction of all medications and verification of the reasons for destruction:
- H. Ensuring that complete and accurate records of the acquisition and disposition of controlled substance medications which have been dispensed for residents of the institutional facility are maintained;
- Attending, within the last two (2) years, a consultant pharmacist seminar which has been approved by the Board;
- J. Maintain consultant pharmacist eligibility as described in Section 1.
- 3. A Long Term Care Facility which is permitted by the Board and where the services of a consultant pharmacist are required shall have the following responsibilities:
 - A. Policy Manual. The institution shall develop policies and procedures regarding pharmacy services which includes, but is-are not limited to, proper labeling of patient medications and emergency drugs, security of patient medications and emergency drugs, administration and controlled substances record-keeping and accountability. This procedural manual shall be the responsibility of the institution and is to be promulgated with the concurrence of the consultant pharmacist, nursing home administrator and the directors of medical and nursing services.
 - B. Reference. Reference materials <u>shall be readily available located</u> in the nursing stations(s) and contain current editions of appropriate reference materials as may be deemed necessary by the consultant pharmacist and the medical and nursing directors.
 - C. Reporting. The institution shall establish policies and procedures which assures that all medication errors and adverse drug reactions are reported immediately to the patient's physician and the consultant pharmacist and an entry made in the patient's record. These procedures should assure that corrective measures are implemented. The consultant pharmacist should be notified within twenty-four (24) hours of discovery of any discrepancy in counts or of a loss of any controlled substances. The consultant pharmacist should notify the Board immediately upon his/her notification with a plan to investigate the loss.
 - D. Emergency Medication Kits. The institution shall establish policies and procedures which assure that the institution is in compliance with ARTICLE XXXV INSTITUTIONAL EMERGENCY MEDICATION KIT PERMITS (FIRST DOSE KITS) FOR LONG TERM CARE FACILITIES AND OTHER APPROVED INSTITUTIONAL FACILITIES of these Pharmacy Practice Regulations.
 - E. Disposal of Patient Medication. The Long Term Care Facility, with the assistance of the consultant pharmacist shall establish policies and procedures which assures the proper disposal of any discontinued, expired, or otherwise unwanted patient medications. Policies and procedures should ensure that any medication removed subject to destruction, does not have a current valid order for the medication on the patient's medication profile. Policies and Procedures for disposal of these

medications should include as follows:

- (1) All unwanted patient medications should remain in a secured location at the institution until proper disposal is made;
- (2) Documentation of any disposal of patient medications should include a paper trail from the time the medication was logged into the discontinued drug storage area until destruction is made. This paper trail shall include a log containing the patient name, medication and strength, and quantity to be destroyed as well as the initials of the person logging in the medication for destruction. This documentation should be stored at the institution and be readily retrievable for inspection by Board Agents for a period of two (2) years;
- (3) Discontinued and unwanted patient medications should shall be destroyed on a timely basis not to exceed ninety sixty (90) (60) days from the date that the medication was discontinued. Any such destruction should shall be performed by two licensed personnel and documented by their signatures. The consultant pharmacist is valid personnel to participate in this activity.
- 4. A consultant pharmacist shall document communication of the findings of his/her reviews to the attending physician and director of nursing along with their responses and maintain these records for a period of two (2) years. A copy of these reviews must be maintained at the facility and available for inspection.

B. UNIT DOSE DISPENSING SYSTEMS FOR (LTCF)

Definitions:

For the purpose of this ARTICLE XXX, the following definitions apply:

- (1) "Provider pharmacist, means a pharmacist licensed to practice pharmacy by the Board who is responsible for supervising the accurate dispensing and proper delivery of medications to a (LTCF) located within this state. These services shall include, at a minimum, proper medication labeling, storage, transport, record keeping, and prospective drug utilization review in compliance with all federal, state and local laws and regulations.
- (2) "Provider Pharmacy" means any pharmacy permitted by the Board where medications are dispensed to residents of a long term care facility located in this state.
- (3) "Single unit dose package" is a package, which contains one discrete pharmaceutical medication dosage form.
- (4) "Unit dose dispensing systems" are those drug medication distribution systems determined by the Board, which involve single unit, unit dose or unit of issue packaging in a manner which helps reduce or remove traditional drug stocks from patient care areas and enables the selection and distribution of medications to be provider pharmacy based and controlled. A unit dose

- dispensing system shall preserve the identity and the integrity of the medication until the time of administration.
- (3) "Unit dose package" is a package, which contains one dose of a medication that particular dose of a medication ordered for the patient for one administration time. for administration to a patient. A unit dose package may contain one or more individual units or fractions of units of a distinct medication is not always a single unit dose package.

(4) "Unit of issue package" is a medication package issued by a provider pharmacy, which provides multiple units/dosages of medications attached to each other but separated in a card or a specifically designed container.

- (5) "Multi-dose strip packaging" (MDS) is a medication package issued by a provider pharmacy which provides multiple distinct medications to be administered at the same time.
- Packaging for all non-sterile medications stored and dispensed in single unit dose, unit dose, unit of issue or MDS packages for use in (LTCF) other than hospitals shall: a LTCF shall:
 - A. Preserve and protect the identity and integrity of the drug medication from the point of packaging to the point of patient administration;
 - B. When packaged by the manufacturer or distributor, be in compliance comply with Federal Food and Drug Administration guidelines;
 - C. Shall be in containers clean and free of extraneous matter when the dosage unit(s) are placed into the package;
 - D. Utilize containers, which are classified according to USP Standard 671 as being Class A or Class B for oral solid dosage forms or is a tight containers for liquid dosage forms.
- 2. Labeling for single unit dose or unit dose packaging or <u>multi-dose strip packaging</u> shall comply with the following;
 - A. Single unit doses or unit doses When packaged by the manufacturer or distributor shall be properly labeled according to Federal Food and Drug Administration requirements;
 - B. Single unit doses or Unit doses or multi-dose strip packaging packaged by the provider pharmacy shall be properly labeled according to ARTICLE XXIX paragraph 7. If needed, the provider pharmacy may utilize an external container to provide required labeling elements. The name of the patient, drug, dosage strength and form must be on the primary packaging.
 - C. Labeling for unit of issue packages shall contain the following information:

 Name and <u>facility specific patient identifier (e.g.</u> room or bed number of patient),
 name of prescribing practitioner, name and strength of drug, directions for use,
 and the name and address of the provider pharmacy when a unit of issue
 package is utilized for patients in an (LTCF) setting.
- 3. If a pharmacist selects a generically equivalent drug product for a brand name drug product prescribed by a practitioner, labeling must comply with ARTICLE X of the

Pharmacy Practice Regulations of the Board.

- 4. Expiration dating for non-sterile medications dispensed and packaged into single unit doses, unit doses, and unit of issue packages shall meet the following conditions:
 - A. Not exceed the manufacturer's original expiration date;
 - B. Have an expiration date assigned based on the unit dose container manufacturer's recommendations;
 - C. May exceed Ninety (90) days from date of repackaging provided that the container is classified according to USP Standard 671 as being Class A or Class B for oral solid dose forms or is a tight container for liquid dosage forms, the container is light resistant when the manufacturer has labeled the drug product "sensitive to light", and the expiration date is not greater than twelve (12) months;
 - D. Drugs or dosage forms having known stability problems or that are not packaged as defined in Article XXX are assigned an expiration date of less than ninety (90) days or are not repackaged as determined by policies developed by the provider pharmacy.

The shortest time span of any of the listed conditions shall be the expiration date assigned to the medication.

C. RETURN OF MEDICATIONS FROM AN LTCF INSTITUTIONAL FACILITY TO THE PROVIDER PHARMACY

- Medication that has been dispensed for a patient residing in an <u>LTCF</u> institutional facility may be returned to the provider pharmacy provided that the medication has an approved reason for return as follows:
 - A. Medication was discontinued prior to delivery;
 - B. Patient no longer a patient or expired prior to medication being delivered;
 - C. Patient in the hospital (discharge status) at time of delivery;
 - D. Medication dosage changed prior to delivery;
 - E. Patient has excessive medications remaining from previous cycle (requires written explanation by the Director of Nurses);
 - F. Medication is considered to be dispensed when it leaves the dispensing pharmacy and is delivered to the institutional facility. LTCF.

Any such-medication subject to return must be intact with no doses removed from blister package (unit dose) and must not have had contact with other medications. Medications, which have been dispensed and placed in bulk packages and accepted by a responsible person at the LTCF, shall not be returned to the dispensing pharmacy for any reason. All medication subject to return, must be returned to the provider pharmacy by pharmacy personnel within five (5) days. No controlled substances may be returned.

The provider pharmacy must implement approved procedures, which ensure that any returned medication has been properly stored, has not been tampered with, and the

integrity of the medication remains intact. Paper trails tracking these procedures must be maintained by the provider pharmacy for a period of two (2) years and be readily retrievable for inspection by agents of the Board.

TITLE 30: PROFESSIONS AND OCCUPATIONS

PART 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS

ARTICLE XXXV INSTITUTIONAL EMERGENCY MEDICATION KIT PERMITS (FIRST DOSE KITS) FOR LONG TERM CARE FACILITIES AND OTHER APPROVED INSITUTIONAL FACILITIES

- Institutions, excluding hospitals, that desire to maintain a stock of prescription drugs provided by a supplying pharmacy for emergency use by patients who are confined to the institution, shall obtain an Institutional Emergency Medication Kit (IEMK) permit from the Mississippi Board of Pharmacy. Emergency use is the procurement of non-patient assigned medications from a stock supply for the purpose of initiating medication therapy or supplying non-routine medications to provide for optimal patient care. Emergency kits as described in this article are not crash carts that are maintained by the institution for resuscitative care.
 - A. Permit. The IEMK permit shall be classified as either a Manual IEMK or an Automated IEMK. The manual IEMK permit is required if the dispensing method is such that the release of each individual dose is not electronically integrated to the documentation required for each such release. An Automated IEMK permit shall be required if the dispensing method is such that the release of each individual dose is electronically integrated to the documentation required for each such releases. Only one (1) type of permit, either Manual or Automated, shall be issued per facility.
 - B. Application for an IEMK permit shall be on a form supplied by the Board. The Application for a Manual IEMK permit shall be accompanied by a fee of One Hundred Dollars (\$100.00) and the Application for an Automated IEMK permit shall be accompanied by a fee of Three Hundred Dollars (\$300.00). A separate permit shall be required for each IEMK and shall be renewed biennially. The Administrator (if a nursing home or other long-term care facility) or business manager of the institution shall make application for the IEMK permit. In the event of a change of the administrator or business manager, a new permit must be obtained. Any IEMK permit renewal application postmarked after December 31 of the renewal period shall be returned and a Fifty Dollar (\$50.00) late renewal fee shall be assessed prior to renewal.
 - C. IEMK Inventory and Accountability
 - (1) The contents of the IEMK are supplied by a pharmacy permitted by the Board. Only one supplying pharmacy may be utilized per facility;
 - (2) The contents of the IEMK are jointly determined by the consultant pharmacist, medical director, director of nurses and the pharmacist supplying the IEMK;
 - (3) The IEMK shall have a "par value" for each prepackaged product that is stored in the IEMK;
 - (4) A copy of the inventory of the IEMK is on file in the institution and at the provider pharmacy and a physical inventory shall be taken at least annually;
 - (5) A Manual IEMK permit authorizes an inventory up to sixty (60) medication items with a limit on the quantity (or par value) to no more than fifteen (15) units each of the sixty (60) medication items. A facility may choose to increase six (6) of the medication items to a maximum of thirty (30) units for those six (6) items. A

maximum of ten (10) medication items may be controlled substances with a maximum limit of ten (10) units each. A facility that requires more than one manual IEMK based on facility design or divergent patient populations may request consideration for an additional manual permit. Without multiple permits, manual IEMK's are globally restricted to the total quantity and drug counts for all kits combined. An Automated IEMK permit shall not have any limits on the quantity of the inventory, except controlled substances shall be limited to a maximum of twenty (20) medication items with a maximum limit of twenty (20) units each; each automated IEMK location requires an additional permit for the facility.

- (6) An IEMK withdrawal log shall be maintained at the institution and all withdrawals of medications from the IEMK shall be documented as follows:
 - (a) name and room number of resident/patient;
 - (b) drug name, strength, and number of units withdrawn;
 - (c) date and time of withdrawal; and
 - (d) name of person withdrawing the medication.
- 2. Use. Emergency kit medications shall be administered to patients only for emergencies and when medications are otherwise unavailable pursuant to a valid medication order or prescription. Providing a patient starting dose(s) of a new medication regimen until available from the provider pharmacy would be considered a valid emergency. Controlled substances may only be administered by licensed healthcare professionals.
- Storage and Security. The IEMK shall be maintained in a securely locked room or cabinet
 at the institution. Access to the contents of the IEMK shall be limited to those licensed
 personnel designated by the director of nurses and the provider pharmacist.
- 4. Controlled Substances. An IEMK that contains controlled substances as allowed per 45 FR24128 (Schedule II, III, IV and V) shall be subject to the following:
 - A. The institution has been issued a controlled substance registration by the Mississippi Board of Pharmacy;
 - B. Controlled substances are stored in a separate locked container; and
 - C. The withdrawal of controlled substances shall comply with the Mississippi Pharmacy Practice Regulations and the Drug Enforcement Administration Regulations which includes a signed prescription by the provider.

TITLE 30: PROFESSIONS AND OCCUPATIONS

PART 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS

ARTICLE XXXV INSTITUTIONAL EMERGENCY MEDICATION KIT PERMITS (FIRST DOSE KITS) FOR LONG TERM CARE FACILITIES AND OTHER APPROVED INSITUTIONAL FACILITIES

- 1. Institutions, excluding hospitals, that desire to maintain a stock of prescription drugs <u>provided</u> by a supplying pharmacy for emergency use by patients who are confined to the institution, shall obtain an Institutional Emergency Medication Kit (IEMK) permit from the Mississippi Board of Pharmacy. Emergency use is the procurement of non-patient assigned medications from a stock supply for the purpose of initiating medication therapy or supplying non-routine medications to provide for optimal patient care. <u>Emergency kits as described in this article are not crash carts that are maintained by the institution for resuscitative care.</u>
 - a. Permit. The IEMK permit shall be classified as either a Manual IEMK or an Automated IEMK. The manual IEMK permit is required if the dispensing method is such that the release of each individual dose is not electronically integrated to the documentation required for each such release. An Automated IEMK permit shall be required if the dispensing method is such that the release of each individual dose is electronically integrated to the documentation required for each such releases. Only one (1) type of permit, either Manual or Automated, shall be issued per facility.
 - b. Application for an IEMK permit shall be on a form supplied by the Board. The Application for a Manual IEMK permit shall be accompanied by a fee of One Hundred Dollars (\$100.00) and the Application for an Automated IEMK permit shall be accompanied by a fee of Three Hundred Dollars (\$300.00). A separate permit shall be required for each IEMK and shall be renewed biennially. The Administrator (if a nursing home or other long-term care facility) or business manager of the institution shall make application for the IEMK permit. In the event of a change of the administrator or business manager, a new permit must be obtained. Any IEMK permit renewal application postmarked after December 31 of the renewal period shall be returned and a Fifty Dollar (\$50.00) late renewal fee shall be assessed prior to renewal.
 - c. IEMK Inventory and Accountability
 - i.The contents of the IEMK are supplied by a pharmacy permitted by the Board. Each IEMK shall be supplied by oOnly one supplying pharmacy may be utilized per facility;
 - ii. The contents of the IEMK are jointly determined by the consultant pharmacist, medical director, director of nurses and the pharmacist supplying the IEMK;
 - iii.The IEMK shall have a "par value" for each prepackaged product that is stored in the IEMK;
 - iv. A copy of the inventory of the IEMK is on file in the institution and at the provider pharmacy and a physical inventory shall be taken at least annually;
 - v.A Manual IEMK permit authorizes an inventory up to sixty (60) medication items with a limit on the quantity (or par value) to no more than fifteen (15) units each of the sixty (60) medication items. A facility may choose to increase six (6) of the medication items to a maximum of thirty (30) units for those six (6) items.

A maximum of ten (10) medication items may be controlled substances with a maximum limit of ten (10) units each. A facility that requires more than one manual IEMK based on facility design or divergent patient populations may request consideration for an additional manual permit. Without multiple permits, manual IEMK's are globally restricted to the total quantity and drug counts for all kits combined. An Automated IEMK permit shall not have any limits on the quantity of the inventory, except controlled substances shall be limited to a maximum of twenty (20) medication items with a maximum limit of twenty (20) units each; each automated IEMK location requires an additional permit for the facility.

- vi.An IEMK withdrawal log shall be maintained at the institution and all withdrawals of medications from the IEMK shall be documented as follows:
 - name and room number of resident/patient;
 - 2. drug name, strength, and number of units withdrawn;
 - 3. date and time of withdrawal; and
 - 4. name of person withdrawing the medication.
- 2. Use. Emergency kit medications shall be administered to patients only for emergencies and when medications are otherwise unavailable pursuant to a valid medication order or prescription. Providing a patient starting dose(s) of a new medication regimen until available from the provider pharmacy would be considered a valid emergency. Controlled substances may only be administered by licensed healthcare professionals.
- 3. Storage and Security. The IEMK shall be maintained in a securely locked room or cabinet at the institution. Access to the contents of the IEMK shall be limited to those licensed personnel designated by the director of nurses and the provider pharmacist.
- 4. Controlled Substances. An IEMK that contains controlled substances <u>as allowed per 45 FR24128</u> (Schedule II, III, IV and V) shall be subject to the following:
 - a. The institution has been issued a controlled substance registration by the Mississippi Board of Pharmacy;
 - b. Controlled substances are stored in a separate locked container; and
 - c. The withdrawal of controlled substances shall comply with the Mississippi Pharmacy Practice Regulations and the Drug Enforcement Administration Regulations which includes a signed prescription by the provider.

On November 16, 2023, came the matter of Eugene F. Brown, Jr., Pharmacist Certificate of Registration Number E-08931, herein also referred to as Respondent, pursuant to a "Notice of Hearing and Complaint" filed by the Mississippi Board of Pharmacy. Board members Jillian Foster and Tony Waits served on the IRC and did not participate in the hearing. Board member David Hudson recused himself and did not participate in the decision.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE MATTER OF:

EUGENE F. BROWN, JR. 10050 ROAD 547 PHILADELPHIA, MS 39350

LICENSE TO PRACTICE PHARMACY NUMBER E-08931

JURISDICTION

The Mississippi Board of Pharmacy has jurisdiction of the subject matter and person of Eugene F. Brown, Jr., Pharmacist Certificate of Registration Number E-08931, pursuant to Section 73-21-97 (1)(f), Mississippi Code of 1972, Annotated.

STATEMENT OF CHARGES

Eugene F. Brown, Jr., Pharmacist Certificate of Registration Number E-08931, is alleged to have committed the following violations:

Count 1:

Mississippi Board of Pharmacy Administrative Rules, Rule 2.1 A. 10:

The Board may refuse to issue or renew, or may suspend, reprimand, revoke or restrict the license, registration or permit or any person upon one or more of the following grounds:

- A. Unprofessional conduct. Unprofessional conduct shall include, but not be limited to:
 - 10. Filing a claim or assisting in the filing of a claim for reimbursement for drugs or professional services which were not provided or which were not authorized to be provided

Specifically, Eugene F. Brown, Jr., disclosed during a public hearing of the board that he would sometimes bill for brand name products but actually dispense generic products. The products in question were Adderall, Concerta, and Suboxone based on hearing testimony, the previous audit, and PMP reports. Agent Brad Hammons and Agent Raymond Keith travelled to Brown's Discount Drugs to investigate these claims. Thirty-four (34) reprinted prescription labels were reviewed since they contained the information needed and Eugene Brown, Jr was not able to run dispensing information directly from the software system. A request was made to wholesalers for any medications ordered corresponding to the thirty-four prescriptions. Wholesaler information obtained showed no brand name Suboxone, Concerta, or Adderall was purchased by Brown's Discount Drugs between February

27, 2021 and May 30, 2023. An inventory completed on February 27, 2021 following a robbery showed there was no brand name Suboxone, Concerta, or Adderall purchases or inventory in stock.

Count 2:

Mississippi Board of Pharmacy Administrative Rules, Rule 2.1 D:

Fraud or intentional misrepresentation by a licensee, registrant or permit holder in securing the issuance or renewal of a license, registration or permit;

Specifically, Eugene Brown, Jr. did not disclose that he had been arrested in November 2020 on his pharmacist renewal application in December 2020. The arrest was executed by the Philadelphia Police Department for simple assault-attempt by physical menace to create fear. Additionally, Mr. Brown, Jr was arrested in February 2022 for lack of rabies inoculation of dogs and cats. He did not disclose this arrest on his December 2022 renewal application.

FINDINGS OF FACT

The Mississippi Board of Pharmacy, after being presented clear and convincing evidence, makes the following findings of fact:

- (1) The Respondent was properly notified of the charges by a duly processed "Notice of Hearing and Complaint" along with a sworn affidavit detailing those charges as provided for in Section 73-21-99, Mississippi Code of 1972, Annotated, and the Respondent has been afforded all due process required by law.
- (2) The Respondent was issued a license to practice pharmacy by the Board, Certificate of Registration Number E-08931, and as such was subject to jurisdiction of the Board pursuant to Section 73-21-97 (l)(f), Mississippi Code of 1972, Annotated.
- (3) The Respondent committed the violations as charged under Count (2). The Board makes no finding with respect to Count (1).

FINAL ORDER OF THE BOARD

This ORDER OF THE BOARD is effective immediately. A certified copy of this ORDER shall be served on the Respondent and a copy maintained on file in the office of the Board.

- Pursuant to Mississippi Code Annotated Section 73-21-103 (l)(d)(i), Respondent shall pay a monetary penalty in the amount of One Thousand Dollars (\$1,000.00) for the first violation of Count 2.
- Pursuant to Mississippi Code Annotated Section 73-21-103 (l)(d)(ii), Respondent shall pay a
 monetary penalty of One Thousand Dollars (\$1,000.00) for the second violation of Count 2.
- Pursuant to Mississippi Code Annotated Section 73-21-103 (l)(d)(iii), Respondent shall pay the cost of investigation and conduct of a proceeding in the amount of Three Hundred Five Dollars and Eighty-Six Cents (\$305.86).
- The total monetary penalty of Two Thousand Three Hundred Five Dollars and Eighty-Six Cents (\$2,305.86) is due and payable in the office of the Board within thirty (30) days of receipt of this Order. The monetary penalty shall be paid electronically through the Board of Pharmacy licensing system or by certified check, attorney's check or money order issued by

a usual, customary, and reputable issuer (U.S. Postal Money Order, Western Union Money Order, etc.).

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ORDERED AND AGREED TO, this the 16th day of November 2023.

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Ronnie Bagwell, President
Tony Waits, Vice-President
Jillian Foster, Secretary
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Michael Gilbow
Fu ()
Ryan Harper
David Hall
David Hudson
Craig Sartin

On November 16, 2023, came the matter of Pharmcore, Inc. dba Hallandale Pharmacy, Permit to operate as a Pharmacy, Permit Number 15930/7.1, herein also referred to as Respondent, pursuant to a "Notice of Hearing and Complaint" filed by the Mississippi Board of Pharmacy. Board members Ryan Harper and Craig Sartin served on the Investigative Review Committee and did not participate in this hearing.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE MATTER OF:

PHARMCORE, INC. DBA HALLANDALE PHARMACY 2666 SW 36TH STREET DANIA, FL 33312

PERMIT TO OPERATE AS A PHARMACY JURISDICTION

The Mississippi Board of Pharmacy has jurisdiction of the subject matter and person of Pharmacore, Inc. dba Hallandale Pharmacy (Hallandale Pharmacy), Permit to Operate as a Pharmacy, Permit Number 15930/7.1, pursuant to Section 73-21-97(1)(f), Mississippi Code of 1972, Annotated.

STATEMENT OF CHARGES

Hallandale Pharmacy is alleged to have committed a violation of the Mississippi Board of Pharmacy Practice Regulations, ARTICLE XXXI.1.A which provides in relevant part:

1. GENERAL PROVISIONS

- A. Prior to engaging in the compounding of pharmaceuticals, a pharmacy shall obtain a compounding certificate from the Mississippi Board of Pharmacy.
 - To obtain a compounding certificate, an applicant must complete a compounding certificate application.
 - ii. A compounding certificate will expire when the pharmacy permit expires and can be renewed at the time a pharmacy permit is renewed.
 - iii. Compounding, without obtaining the compounding certificate, shall be grounds for disciplinary action.
 - iv. Every pharmacy that engages in compounding shall submit a compounding statistical report to the Board on or about January 31st of each year on a form prescribed by the Board.
 - v. Failure to submit the report as required by this regulation shall be grounds for disciplinary action.
 - vi. A compounding certificate shall become inactive if a pharmacy fails to compound any prescriptions in a calendar year. A pharmacy may not compound prescriptions with an inactive compounding certificate. A pharmacy may petition the Board to activate a compounding certificate that is inactive.
 - vii. Any pharmacy with an active compounding certificate is subject to a compounding inspection by the Board.

Specifically, Hallandale Pharmacy applied for a compounding certificate from the Mississippi Board of Pharmacy in September 2019. Hallandale Pharmacy was notified on December 27, 2019, that the compounding certificate application was denied due to an unsatisfactory inspection report and a new application could be submitted with a new inspection report. Hallandale Pharmacy was also notified that no compounded prescription medication could be shipped into Mississippi until a compounding certificate was obtained. In December of 2021, Hallandale Pharmacy submitted another compounding certificate application. On December 20, 2021, this application was also denied. Despite not having a compounding certificate, Hallandale Pharmacy shipped compounded prescription medication to patients in Mississippi in violation of the Mississippi Board of Pharmacy Practice Regulations, ARTICLE XXXI in 2020, 2021, 2022 and 2023.

FINDINGS OF FACT

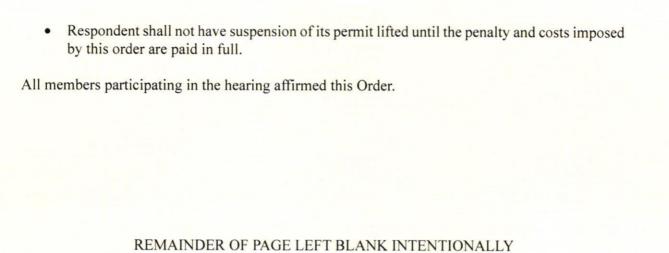
The Mississippi Board of Pharmacy, after being presented clear and convincing evidence, makes the following findings of fact:

- (1) The Respondent was properly notified of the charges by a duly processed "Notice of Hearing and Complaint" along with a sworn affidavit detailing those charges as provided for in Section 73-21-99, Mississippi Code of 1972, Annotated, and the Respondent has been afforded all due process required by law.
- (2) The Respondent was subject to jurisdiction of the Board pursuant to Section 73-21-97 (l)(f), Mississippi Code of 1972, Annotated.
- (3) The Respondent committed the violation as charged and shipped compounded prescription medication into the State of Mississippi without a compounding certificate in 2020, 2021, 2022 and 2023.

FINAL ORDER OF THE BOARD

This ORDER OF THE BOARD is effective immediately. A certified copy of this ORDER shall be served on the Respondent and a copy maintained in the office of the Board.

- Pursuant to Section 73-21-103 (1)(a), the permit of Respondent is suspended for a period of three (3) years from the date of this Order. The Respondent shall appear before the Board to request the suspension of the Respondent's permit be lifted.
- Pursuant to Section 73-21-103(1)(d)(i), Mississippi Code of 1972, Annotated, Respondent shall pay a monetary penalty in the amount of One Thousand Dollars (\$1,000.00) for a violation of Count 1 for the year 2020.
- Pursuant to Section 73-21-103(1)(d)(ii), Mississippi Code of 1972, Annotated, Respondent shall pay a monetary penalty in the amount of Five Thousand Dollars (\$5,000.00) for a violation of Count 1 for the years 2021, 2022 and 2023 for a total of Fifteen Thousand Dollars (\$15,000.00).
- Pursuant to Section 73-21-103 (1)(d)(iii), Respondent shall pay the cost of investigation and proceeding in the amount of Two Hundred Fifty Dollars (\$250.00).
- The total monetary penalty and cost of investigation shall be Sixteen Thousand Two Hundred Fifty Dollars (\$16,250.00). The monetary penalty shall be paid electronically through the Board of Pharmacy licensing system or by certified check, attorney's check or money order issued by a usual, customary, and reputable issuer (U.S. Postal Money Order, Western Union Money Order, etc.).



ORDERED AND AGREED TO, this the 16th day of November 2023.

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Ronnie Bagwell, President
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Tony Waits, Vice-President
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Jillian Foster, Secretary
Michal G allen
Michael Gilbow
Fu ()
Ryan Harper
David Halo
David Hudson
Craig Sartin

On November 16, 2023, came the matter of Billy R. Calvert, Pharmacist Certificate of Registration Number E-06750, herein also referred to as Respondent, pursuant to a "Notice of Hearing and Complaint" filed by the Mississippi Board of Pharmacy.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE MATTER OF:

BILLY R. CALVERT 207 DUCK COVE MADISON, MS 39110

LICENSE TO PRACTICE PHARMACY NUMBER E-06750

JURISDICTION

The Mississippi Board of Pharmacy has jurisdiction of the subject matter and person of Billy R. Calvert, Pharmacist Certificate of Registration Number E-06750, pursuant to Section 73-21-97 (1)(f), Mississippi Code of 1972, Annotated.

STATEMENT OF CHARGES

Billy R. Calvert, Pharmacist Certificate of Registration Number E-06750, is alleged to have committed the following violations:

Mississippi Board of Pharmacy Administrative Rules, Rule 2.1 F:

F. Violation of any of the provisions of the Mississippi Pharmacy Practice Act or rules or regulations adopted pursuant to such Act; or violation of pharmacy or drug laws of any other state or the federal government or the rules/regulations pertaining thereto;

Mississippi Pharmacy Practice Regulations, ARTICLE VII, RESPONSIBILITY OF PHARMACIST-IN-CHARGE (PIC), Paragraph 1. A:

- 1. The person who signs the application for a pharmacy permit or the renewal of a pharmacy permit shall be the pharmacist-in-charge (PIC) for that facility.
 - A. Authority. The PIC of the pharmacy shall be responsible for complete supervision, management and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy in the entire prescription department. He/She shall have the cooperation and support of all pharmacy staff in carrying out these responsibilities. The pharmacist-in-charge is responsible for assuring that all personnel are properly registered or licensed with the Board and that all pharmacy permits are current and appropriate for the type of pharmacy operation being conducted. A pharmacist shall not be the PIC at more than one Community Pharmacy or Institutional I Pharmacy (unless the Board grants a waiver upon presentation of good cause) and shall not be the pharmacist-in-charge or have personal supervision of more than one facility which is open to the general public on a full-time basis.

Count 1:

Violation of Mississippi Pharmacy Practice Regulations, ARTICLE VIII, RESPONSIBILITY OF PHARMACIST/PHARMACIST CARE, Paragraph 1. C. (2):

- 1. In the dispensing of drugs, the pharmacist shall have the following responsibilities:
 - C. In the dispensing of medications for ambulatory (or outpatients):
 - (2) The pharmacist shall be present and personally supervising the activities of the pharmacy technician at all times;

Specifically, Keisha Fuller, Pharmacy Technician Registration #PT-213332, admitted that she worked in the pharmacy and even dispensed prescriptions when there was no pharmacist present. Billy R. Calvert, Pharmacist License #E-06750, the pharmacist-in-charge, admitted that Fuller had been in the pharmacy without pharmacist supervision.

Count 2:

Violation of Mississippi Pharmacy Practice Regulations, ARTICLE XI, STOCK CONTAINER LABELING, OUTDATED MERCHANDISE, SANITATION, DISPENSING AND STORAGE REQUIREMENTS, Paragraph 4:

4. A pharmacist or a pharmacy shall not accept the return for subsequent resale or exchange any drug after such drug has been taken from the premises where sold, distributed or dispensed and from the control of the pharmacist.

Specifically, Billy R. Calvert, Pharmacist License #E-06750, the pharmacist-in-charge, acknowledged that he accepted returns of controlled substances from patients of drugs not only dispensed by Sports Medicine Pharmacy, but also dispensed from other pharmacies. Keisha Fuller, Pharmacy Technician Registration #PT-213332, stated that some of this medication was used to dispense to patients when the pharmacy was out of a specific drug.

Count 3:

Violation of Mississippi Pharmacy Practice Regulations, ARTICLE XIX, DISPENSING OF SCHEDULE II CONTROLLED SUBSTANCES, Paragraphs 1. A, B:

- A pharmacist may dispense a Schedule II controlled substance only pursuant to a valid written prescription/order signed by the prescribing practitioner except as described as follows:
 - A. When a Schedule II controlled substance is needed in a situation in which a written prescription cannot reasonably be obtained, it may be considered an emergency situation and a pharmacist may dispense a Schedule II controlled substance pursuant to an oral prescription of a practitioner. A Schedule II controlled substance prescription given in this manner shall be reduced to writing by the pharmacist and shall be for a quantity of medication sufficient for the emergency period, not to exceed 48 hours. Within seven (7) days of the receipt of an oral prescription for a Schedule II controlled substance, the pharmacist shall obtain a prescription signed by the prescribing practitioner for the

- medication dispensed. This prescription shall be attached to the copy of the prescription prepared by the pharmacist pursuant to the prescriber's oral order.
- B. A prescription for a controlled substance in Schedule II may be transmitted from the prescribing practitioner to a pharmacy via facsimile provided the original signed prescription is presented to the pharmacist for review prior to dispensing of the controlled substance. The original prescription shall be maintained in accordance with ARTICLE XIII of these regulations.

Specifically, Billy R. Calvert, Pharmacist License #E-06750, admitted that there were instances when he filled controlled substance prescriptions without a prescriber's signature.

Count 4:

Violation of Mississippi Pharmacy Practice Regulations ARTICLE XXIII, RECORD KEEPING ON CONTROLLED SUBSTANCES, Paragraph 1:

1. Every facility permitted by the Board of Pharmacy shall keep complete and accurate records of the acquisition and disposition of all controlled substances. Records of acquisition must be maintained for a period of two (2) years. Records of disposition must be maintained for a period of six (6) years.

These records shall include:

- A. A current dated and signed inventory of all controlled substances on hand on the inventory date;
- B. Complete and accurate records of receipt of all controlled Substances;
- C. Complete and accurate records of disposition of all controlled substances.

These records shall be kept in such a manner that an audit will show the beginning inventory and record of acquisition of controlled substances to balance with the controlled substances on hand and the record of disposition of controlled substances.

Specifically, Billy R. Calvert, Pharmacist License #E-06750, the pharmacist-in-charge, acknowledged that he accepted returns of controlled substances from patients of drugs not only dispensed by Sports Medicine Pharmacy, but also dispensed from other pharmacies. Sports Medicine Pharmacy, Pharmacy Permit Number 14908/2.0, did not have any records of acquisition or disposition of these controlled substances.

Count 5:

Violation of Mississippi Pharmacy Practice Regulations, ARTICLE XXIV, SECURITY OF CONTROLLED SUBSTANCES, Paragraph 1:

1. In all places where controlled substances are maintained, they shall be maintained in a manner to deter loss by theft or burglary. When a person who has a controlled substances registration with the Board of Pharmacy has a loss of controlled substances, the Board may issue an order to that person to appear before the Board to present a plan to the Board that is designed to prevent further loss of controlled substances, or he/she may be ordered by the

Board to implement any other reasonable measure to improve security on controlled substances as deemed necessary by the Board to prevent further loss of controlled substances.

Specifically, Keisha Fuller, Pharmacy Technician Registration #PT-213332, admitted to taking stock bottles of Alprazolam 1mg XR and Buspirone from Sports Medicine Pharmacy, Pharmacy Permit Number 14908/2.0, and had them at her house. Billy R. Calvert, Pharmacist License #E-06750, the pharmacist-in-charge, admitted that he knew Fuller had a key to the pharmacy and the code to the pharmacy safe.

Count 6:

Violation of Mississippi Pharmacy Practice Regulations, ARTICLE XXVI, DISPOSAL OF CONTROLLED SUBSTANCES, Paragraph 1, 4:

- 1. Any registrant of the Board authorized to possess controlled substances in the course of their professional practice or the course of their business may dispose of any expired, excess, or unwanted controlled substances by contacting and utilizing the services of a reverse distributor as defined by the Federal Drug Enforcement Administration. Any such reverse distributor must hold a valid Certificate of Registration Number issued by the Federal Drug Enforcement Administration and the Mississippi Board of Pharmacy. All records of the disposal of controlled substances shall be maintained for a period of two (2) years.
- 4. Except as provided for in this ARTICLE, no controlled substance may be destroyed or disposed of by a registrant without written permission of the Regional Director of the Federal Drug Enforcement Administration.

Specifically, Billy R. Calvert, Pharmacist License #E-06750, the pharmacist-in-charge, stated that he accepted returns of controlled substances from patients of drugs not only dispensed by Sports Medicine Pharmacy, but also dispensed from other pharmacies. He stated that he would dispose of these controlled substances by either flushing them or taking them to the DEA take back day.

Count 7:

Violation of Mississippi Board of Pharmacy Administrative Rule 2.1 P:

P. Termination of employees suspected of theft of pharmaceuticals or merchandise without contacting the Board prior to termination;

Specifically, Keisha Fuller, Pharmacy Technician Registration #PT-213332, was terminated for embezzlement in early March 2023 but Billy R. Calvert, Pharmacist License #E-06750, the pharmacist-in-charge, never reported the termination to the Mississippi Board of Pharmacy.

SETTLEMENT AGREEMENT

Pursuant to discussions between Board Counsel and Counsel for the Respondent, an Agreement to Settle this matter is found to be in the best interest of all parties involved. It is hereby Agreed as follows:

FINDINGS OF FACT

The Mississippi Board of Pharmacy, after being presented clear and convincing evidence, makes the following findings of fact:

(1) The Respondent was properly notified of the charges by a duly processed "Notice of Hearing and Complaint" along with a sworn affidavit detailing those charges as provided for in Section 73-21-99, Mississippi Code of 1972, Annotated, and the Respondent has been afforded all due process required by law.

(2) The Respondent was issued a license to practice pharmacy by the Board, Certificate of Registration Number E-06750, and as such was subject to jurisdiction of the Board pursuant

to Section 73-21-97 (l)(f), Mississippi Code of 1972, Annotated.

(3) The Respondent does not contest the violations as charged. This Settlement Agreement is entered into solely for the purpose of resolving the stated matters in a manner mutually satisfactory to the Respondent and the Board. This Settlement Agreement shall not serve as precedent for resolving any other complaints, grievances, appeals or actions, which have been or may be filed.

(4) The Respondent agrees to the disciplinary action stated below as imposed by the Board.

FINAL ORDER OF THE BOARD

This ORDER OF THE BOARD is effective immediately. A certified copy of this ORDER shall be served on the Respondent and a copy maintained on file in the office of the Board.

- Pursuant to Mississippi Code Annotated Section 73-21-103 (l)(c). Respondent shall be restricted from serving as the pharmacist-in-charge for any facility permitted by the Board. In addition, the Respondent shall be prohibited from performing any pharmacy duties or responsibilities for Sports Medicine Pharmacy, Permit Number 14908/2.0.
- Pursuant to Mississippi Code Annotated Section 73-21-103 (l)(d)(i), Respondent shall pay a
 monetary penalty in the amount of One Thousand Dollars (\$1,000.00) for the violation of
 Count 1.
- Pursuant to Mississippi Code Annotated Section 73-21-103 (l)(d)(ii), Respondent shall pay a
 monetary penalty of Two Thousand Dollars (\$2,000.00) for violation each of the six (6)
 subsequent counts for a total of Twelve Thousand Dollars (\$12,000.00).
- Pursuant to Mississippi Code Annotated Section 73-21-103 (l)(d)(iii), Respondent shall pay
 the cost of investigation and conduct of a proceeding in the amount of One Thousand One
 Hundred Ninety-One Dollars and Ninety-One Cents (\$1,191.91).
- The total monetary settlement of Fourteen Thousand One Hundred Ninety-One Dollars and Ninety-One Cents (\$14,191.91) is due and payable in the office of the Board within thirty (30) days of receipt of this Order.

I hereby agree to the findings and terms of this Agreed Order:

Billy R. Calvert

SUBSCRIBED AND SWORN TO, in my presence, this 6 day of Novem her, 2023.

Ole M Wash
NOTARY PUBLIC

MY COMMISSION EXPIRES:

Pecember 15, 2025



ORDERED AND AGREED TO, this the 16th day of November 2023.

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Ronnie Bagwell, President
Tony Waits, Vice-President
Jillian Foster, Secretary
Michael Gilbow
Hichael Gilbow
Ryan Harper
David Hudson
Craig Sartin

On November 16, 2023, came the matter of Billy R. Calvert, Pharmacist Certificate of Registration Number E-06750, herein also referred to as Respondent, pursuant to a "Notice of Hearing and Complaint" filed by the Mississippi Board of Pharmacy. Board members Jillian Foster and Tony Waits served on the IRC and did not participate in the hearing. Board member Mike Gilbow did not participate in the decision.

BEFORE THE MISSISSIPPI BOARD OF PHARMACY

IN THE MATTER OF:

BILLY R. CALVERT 207 DUCK COVE MADISON, MS 39110

LICENSE TO PRACTICE PHARMACY NUMBER E-06750

JURISDICTION

The Mississippi Board of Pharmacy has jurisdiction of the subject matter and person of Billy R. Calvert, Pharmacist Certificate of Registration Number E-06750, pursuant to Section 73-21-97 (1)(f), Mississippi Code of 1972, Annotated.

STATEMENT OF CHARGES

Billy R. Calvert, Pharmacist Certificate of Registration Number E-06750, is alleged to have committed the following violations:

Mississippi Board of Pharmacy Administrative Rules, Rule 2.1 F:

F. Violation of any of the provisions of the Mississippi Pharmacy Practice Act or rules or regulations adopted pursuant to such Act; or violation of pharmacy or drug laws of any other state or the federal government or the rules/regulations pertaining thereto;

Mississippi Pharmacy Practice Regulations, ARTICLE VII, RESPONSIBILITY OF PHARMACIST-IN-CHARGE (PIC), Paragraph 1. A:

- 1. The person who signs the application for a pharmacy permit or the renewal of a pharmacy permit shall be the pharmacist-in-charge (PIC) for that facility.
 - A. Authority. The PIC of the pharmacy shall be responsible for complete supervision, management and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy in the entire prescription department. He/She shall have the cooperation and support of all pharmacy staff in carrying out these responsibilities. The pharmacist-in-charge is responsible for assuring that all personnel are properly registered or licensed with the Board and that all pharmacy permits are current and appropriate for the type of pharmacy operation being conducted. A pharmacist shall not be the PIC at more than one Community Pharmacy or Institutional I Pharmacy (unless the Board grants a waiver upon presentation of good cause) and shall not be the pharmacist-in-charge or have personal supervision of more than one facility which is open to the general public on a full-time basis.

Count 1:

Violation of Mississippi Pharmacy Practice Regulations, ARTICLE XXIII RECORDKEEPING ON CONTROLLED SUBSTANCES, Paragraph 1:

Every facility permitted by the Board of Pharmacy shall keep complete and accurate records
of the acquisition and disposition of all controlled substances. Records of acquisition must be
maintained for a period of two (2) years. Records of disposition must be maintained for a
period of six (6) years.

These records shall include:

- A. A current dated and signed inventory of all controlled substances on hand on the inventory date;
- B. Complete and accurate records of receipt of all controlled substances;
- C. Complete and accurate records of disposition of all controlled substances.

These records shall be kept in such a manner that an audit will show the beginning inventory and record of acquisition of controlled substances to balance with the controlled substances on hand and the record of disposition of controlled substances.

Specifically, on June 30, 2023, the Compliance Division of the Mississippi Board of Pharmacy performed a count of the controlled substance inventory at The Surgery Center at Mississippi Sports Medicine, Pharmacy Permit Number 12956/13.3. A comparison of the physical count and the perpetual inventory revealed the pharmacy was short fifty (50) vials of meperidine 25 mg and ninety-five (95) vials of midazolam 5 mg/ML.

Count 2:

Violation of Mississippi Pharmacy Practice Regulations, ARTICLE XXIII RECORDKEEPING ON CONTROLLED SUBSTANCES, Paragraph 3:

3. If a pharmacy utilizes a data processing system it must provide immediate retrieval of original prescription order information for those prescription orders which are currently authorized for refilling and of the refill history for the past six months for controlled substances prescription orders. The data processing system must have the capability of producing a hard copy printout of this information. The data processing system must also have the capability of producing a hard copy printout of all dispensing information required to be kept by the pharmacy, including an audit trail for any specified strength and dosage form of any controlled substance either by brand name or generic name or both for any time period in the prior two (2) years. The audit trail specified by this Article must be produced on verbal or written request of any Compliance Agent of the Board. Failure to produce and provide this audit trail within twenty-four (24) hours, constitutes prima facie evidence of failure to keep and maintain records as defined in paragraph 1., C., of this ARTICLE.

Specifically, on June 30, 2023, the Compliance Division of the Mississippi Pharmacy Board attempted to conduct an audit of the controlled substances at The Surgery Center at Mississippi Sports Medicine, Pharmacy Permit Number 12956/13.3. The pharmacy was unable to supply a report of the controlled substance dispensing for the last two weeks of June 2022. As the pharmacist-in-charge of The Surgery Center at Mississippi Sports Medicine, Pharmacy Permit Number 12956/13.3, Billy R. Calvert was responsible for compliance with the recordkeeping regulations.

FINDINGS OF FACT

The Mississippi Board of Pharmacy, after being presented clear and convincing evidence, makes the following findings of fact:

(1) The Respondent was properly notified of the charges by a duly processed "Notice of Hearing and Complaint" along with a sworn affidavit detailing those charges as provided for in Section 73-21-99, Mississippi Code of 1972, Annotated, and the Respondent has been afforded all due process required by law.

(2) The Respondent was issued a license to practice pharmacy by the Board, Certificate of Registration Number E-06750, and as such was subject to jurisdiction of the Board pursuant to Section 73-21-97 (l)(f), Mississippi Code of 1972, Annotated.

(3) The Respondent committed the violations as charged.

FINAL ORDER OF THE BOARD

This ORDER OF THE BOARD is effective immediately. A certified copy of this ORDER shall be served on the Respondent and a copy maintained on file in the office of the Board.

- Pursuant to Mississippi Code Annotated Section 73-21-103 (l)(c), the Respondent shall be prohibited from performing any pharmacy duties or responsibilities for The Surgery Center at Sports Medicine Pharmacy, Permit Number 12956/13.3.
- Pursuant to Mississippi Code Annotated Section 73-21-103 (l)(d)(i), Respondent shall pay a
 monetary penalty in the amount of One Thousand Dollars (\$1,000.00) for the violation of
 Count 1.
- Pursuant to Mississippi Code Annotated Section 73-21-103 (l)(d)(ii), Respondent shall pay a
 monetary penalty of Five Thousand Dollars (\$5,000.00) for violation of Count 2.
- Pursuant to Mississippi Code Annotated Section 73-21-103 (l)(d)(iii), Respondent shall pay the cost of investigation and conduct of a proceeding in the amount of Five Hundred Dollars (\$500.00).

The total monetary penalty of Six Thousand Five Hundred Dollars (\$6,500.00) is due and payable in the office of the Board within thirty (30) days of receipt of this Order. The monetary penalty shall be paid electronically through the Board of Pharmacy licensing system or by certified check, attorney's check or money order issued by a usual, customary, and reputable issuer (U.S. Postal Money Order, Western Union Money Order, etc.).

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ORDERED AND AGREED TO, this the 16th day of November 2023.

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Ronnie Bagwell, President
Rolline Dagwell, Fresident
Jan What
Tony Waits, Vice-President
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Alliforin
Jillian Foster, Secretary
Michael G allen
Michael Gilbow
Fu CI
Ryan Harper
David Halo
David Hudson
Craig Sartin